

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form S-4
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933



DIFFUSION PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)
300 East Main Street, Suite 201
Charlottesville, Virginia 22902
(434) 220-0718

30-0645032
(I.R.S. Employer
Identification Number)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Robert J. Cobuzzi, Jr., Ph.D.
President and Chief Executive Officer
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300 East Main Street, Suite 201
Charlottesville, Virginia 22902

(434) 220-0718 (Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement and the satisfaction or waiver of all other conditions under the Merger Agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer)
Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this proxy statement/prospectus/information statement is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This proxy statement/prospectus/information statement is not an offer to sell and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED MAY 10, 2023



PROPOSED MERGER

YOUR VOTE IS VERY IMPORTANT

To the Stockholders of Diffusion Pharmaceuticals Inc. and EIP Pharma, Inc.:

Diffusion Pharmaceuticals Inc., a Delaware corporation ("Diffusion"), EIP Pharma, Inc., a Delaware corporation ("EIP") and Dawn Merger Sub Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Diffusion ("Merger Sub") entered into an Agreement and Plan of Merger, dated as of March 30, 2023 (the "Merger Agreement"). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will merge with and into EIP, with EIP surviving as a wholly-owned subsidiary of Diffusion. These transactions are referred to in this proxy statement/prospectus/information statement collectively as the "Merger." At the effective time of the Merger (the "Effective Time"), Diffusion will be renamed "CervoMed Inc." and, subject to satisfying The Nasdaq Stock Market LLC's initial listing standards, expects to trade on the Nasdaq Capital Market under the symbol "CRVO."

Immediately prior to the Effective Time, EIP's convertible notes ("EIP Convertible Notes") and each of EIP's Series A-1 preferred stock, par value \$0.001, EIP's Series A-2 preferred stock, par value \$0.001, and EIP's Series B preferred stock, par value \$0.001 (collectively, "EIP Preferred Stock") will be converted into common stock of EIP, par value \$0.001 per share ("EIP Common Stock"). At the Effective Time, other than certain excluded shares and dissenting shares, each share of EIP Common Stock will be converted into the right to receive shares of common stock, par value \$0.001 of Diffusion ("Diffusion Common Stock"), equal to the "Exchange Ratio" described in this proxy statement/prospectus/information statement, subject to adjustment to account for the effect of a reverse stock split, if any, of outstanding Diffusion Common Stock, within a range of one new share for not less than and not greater than shares outstanding, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time, as discussed in this proxy statement/prospectus/information statement, and further adjusted based on Diffusion's net cash immediately prior to the closing of the Merger. As of the date of the Merger Agreement, it was estimated that, after giving effect to the transactions contemplated thereby, the Exchange Ratio would be approximately 0.1860 pre-split shares of Diffusion's Common Stock, based on certain assumptions described in this proxy statement/prospectus/information statement. On a post-reverse split basis, the Exchange Ratio would be within a range of approximately to post-split shares of Diffusion Common Stock, holding all other assumptions described in this proxy statement/prospectus/information statement the same.

Applying the Exchange Ratio, immediately following the Effective Time, pre-Merger EIP equity holders are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and the pre-Merger equity holders of Diffusion are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, in each case, subject to certain assumptions, including that net cash (as calculated in accordance with the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million.

The Merger will result in a combined company primarily focused on the advancement of central nervous system ("CNS") focused therapeutics, including EIP's lead drug candidate neflamapimod, which is currently being developed for the treatment of dementia with Lewy bodies ("DLB"). Phase 2a clinical trial results with neflamapimod in DLB that showed statistically significant positive effects compared to placebo on dementia severity and walking ability were published in a major scientific journal in September 2022, and in January 2023, EIP was awarded \$21 million in non-dilutive grant funding from the National Institutes of Health's National Institute on Aging ("NIA") that is expected to fully fund clinical trial costs associated with a planned Phase 2b study evaluating neflamapimod in patients with DLB, a study which EIP anticipates initiating by the end of the second quarter of 2023.

At the Effective Time, each outstanding and unexercised option to purchase shares of EIP Common Stock will be assumed by Diffusion and converted into an option to purchase, on the same terms and conditions, a number of shares of Diffusion Common Stock determined by multiplying (1) the number of shares of EIP Common Stock that were subject to such option, as in effect immediately prior to the Effective Time, by (2) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Diffusion Common Stock, at an exercise price per share determined by dividing (A) the per share exercise price of EIP Common Stock subject to such option, as in effect immediately prior to the effective time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent. At the Effective Time, all outstanding and unexercised warrants to purchase shares of EIP Common Stock outstanding immediately prior to the Merger will be assumed by Diffusion and become exercisable (1) for a number of shares of Diffusion Common Stock equal to the number of shares of EIP Common Stock subject to such warrant immediately prior to the effectiveness of the Merger multiplied by the Exchange Ratio (rounding down to the nearest whole share) and (2) at an exercise price per share of Diffusion Common Stock equal to the exercise price per share of EIP Common Stock applicable immediately prior to the effectiveness of the Merger divided by the Exchange Ratio (rounding up to the nearest whole cent). Diffusion stockholders and option holders will continue to own and hold their existing shares of Diffusion Common Stock and options, respectively. All options and warrants to purchase shares of Diffusion Common Stock that are outstanding immediately prior to the Effective Time will remain outstanding following the Effective Time.

Diffusion Common Stock is currently listed on the Nasdaq Capital Market under the symbol “DFFN.” In connection with The Nasdaq Stock Market LLC (“Nasdaq”) “reverse merger” rules, Diffusion has filed an initial listing application with Nasdaq to seek listing on the Nasdaq Capital Market or other appropriate Nasdaq trading market upon the closing of the Merger. On _____, 2023, the last trading day before the date of this proxy statement/prospectus/information statement, the closing sale price of Diffusion Common Stock was \$ _____ per share.

Diffusion is holding a special meeting of stockholders in order to obtain the stockholder approvals necessary to complete the Merger and related matters. At the Diffusion special meeting, which will be held virtually on _____, 2023 at _____, Eastern Time by means of a live webcast, unless postponed or adjourned to a later date, Diffusion will ask its stockholders:

- to approve pursuant to Nasdaq Listing Rules 5635(a) and 5635(b) (A) the issuance of shares of Diffusion Common Stock pursuant to the Merger, which will represent more than 20% of the shares of Diffusion Common Stock outstanding immediately prior to the Merger, and (B) the change of control resulting from the Merger (the “Stock Issuance Proposal”);
- to approve an amendment to the certificate of incorporation of Diffusion, as amended, to effect a reverse stock split of outstanding Diffusion Common Stock (the “Reverse Split”) at a ratio within a range of one new share for not less than _____ and not greater than _____ shares outstanding, at any time prior to December 31, 2023, the implementation and timing of which shall be subject to the discretion of Diffusion’s board of directors and, if the Merger Agreement is still in effect at such time, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time (the “Reverse Split Proposal”); and
- to approve a postponement or adjournment of the Diffusion special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposals set forth above.

After careful consideration, Diffusion’s board of directors has unanimously adopted resolutions (a) approving the execution, delivery, and performance of the Merger Agreement and the consummation of the transactions contemplated thereby, including the Merger and (b) recommending that the stockholders of Diffusion vote “**FOR**” each of the proposals set forth in this proxy statement/prospectus/information statement.

After careful consideration, EIP’s board of directors has unanimously (a) approved the execution, delivery, and performance of the Merger Agreement and the consummation of the transactions contemplated thereby, including the Merger, (b) deemed it fair to, advisable and in the best interests of, EIP and its stockholders to enter into the Merger Agreement, and (c) resolved to recommend adoption of the Merger Agreement by the stockholders of EIP, in each case, in accordance with the General Corporation Law of the State of Delaware.

Please refer to the attached proxy statement/prospectus/information statement for further information with respect to the business to be transacted at the Diffusion special meeting. As described in this proxy statement/prospectus/information statement, the officers, directors and certain stockholders of EIP who in the aggregate beneficially own or control shares of EIP capital stock necessary to adopt the Merger Agreement and approve the Merger and the related transactions contemplated thereby have entered into support agreements pursuant to which they have agreed to vote such shares in favor of such adoption and approval, subject to the terms of the support agreements. The officers, directors and certain Diffusion stockholders who in the aggregate beneficially own or control less than 1% of the outstanding shares of Diffusion Common Stock have entered into support agreements pursuant to which they have agreed to vote such shares in favor of the Stock Issuance Proposal and the Reverse Split Proposal, subject to the terms of the support agreements. No meeting of EIP stockholders to adopt the Merger Agreement and approve the Merger and related transactions will be held. Instead, all EIP’s stockholders will have the opportunity to vote to adopt the Merger Agreement and approve the Merger and related transactions, by signing and returning to EIP a written consent on or after the effective date of the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part. EIP stockholders, including those who are parties to support agreements, are requested to execute written consents providing such approvals.

More information about Diffusion, EIP and the proposed transactions are contained in this proxy statement/prospectus/information statement. Diffusion and EIP urge you to read this proxy statement/prospectus/information statement carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER “RISK FACTORS” BEGINNING ON PAGE 36.

Diffusion and EIP are excited about the opportunities the Merger brings to both Diffusion and EIP stockholders. Thank you for your consideration and continued support.

Robert J. Cobuzzi, Jr.
President & Chief Executive Officer
Diffusion Pharmaceuticals Inc.

John Alam
President & Chief Executive Officer
EIP Pharma, Inc.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this proxy statement/prospectus/information statement. Any representation to the contrary is a criminal offense.

This proxy statement/prospectus/information statement is dated _____, 2023, and is first being mailed to Diffusion and EIP stockholders on or about _____, 2023.

Diffusion₂n

Pharmaceuticals Inc.

DIFFUSION PHARMACEUTICALS INC.
300 Main Street, Suite 201
Charlottesville, Virginia 22902
(434) 220-0718

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS

To Be Held On _____, 2023

Dear Stockholders of Diffusion:

On behalf of the board of directors of Diffusion Pharmaceuticals Inc., a Delaware corporation (“Diffusion”), Diffusion is pleased to deliver this proxy statement/prospectus/information statement with respect to the Agreement and Plan of Merger, dated as of March 30, 2023 (the “Merger Agreement”), by and among Diffusion, Dawn Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of Diffusion (“Merger Sub”), and EIP Pharma, Inc., a Delaware corporation (“EIP”), pursuant to which, upon the terms and subject to the conditions set forth in the Merger Agreement, EIP will become a wholly-owned subsidiary of Diffusion (the “Merger”). A copy of the Merger Agreement is attached as Annex A to this proxy statement/prospectus/information statement.

There will not be a physical meeting location. The special meeting of stockholders of Diffusion will be held virtually on _____, 2023 at _____, Eastern Time by means of a live audio webcast. Online check-in will begin at _____ Eastern Time, and you should allow ample time for the check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please call the number on the virtual meeting portal landing page for assistance.

The special meeting of stockholders of Diffusion will be held for the following purposes:

1. To consider and vote on a proposal to approve, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), (A) the issuance of shares of Diffusion Common Stock pursuant to the Merger, which will represent more than 20% of the shares of Diffusion Common Stock outstanding immediately prior to the Merger, and (B) the change of control resulting from the Merger (the “Stock Issuance Proposal”);
2. To consider and vote on a proposal to approve an amendment to the certificate of incorporation of Diffusion, as amended, the form of which is attached as Annex B to this proxy statement/prospectus/information statement, to effect a reverse stock split of outstanding Diffusion Common Stock (the “Reverse Split”) at a ratio within a range of one new share for not less than and not greater than shares outstanding, at any time prior to December 31, 2023, the implementation and timing of which shall be subject to the discretion of Diffusion’s board of directors and, if the Merger Agreement is still in effect at such time, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time (the “Reverse Split Proposal”); and
3. To consider and vote on a proposal to approve a postponement or adjournment of the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposals set forth above (the “Postponement Proposal”).

The Diffusion special meeting will be completely virtual and there will be no physical location for Diffusion stockholders to attend. In order to attend the meeting, Diffusion stockholders must pre-register at _____ by _____ Eastern Time on _____, 2023. If you are a Diffusion stockholder holding shares in “street name” through a bank, broker or other nominee, and also wish to vote at the meeting, you will need to obtain from that entity a “legal proxy” and submit it when you register. After you register, you will receive an email with a unique link and password that will allow you to attend the meeting. If your shares are held in “street name” and you provided a legal proxy when you registered, that email will also contain a control number that will allow you to vote at the meeting. If you hold your shares through Diffusion’s transfer agent, use the control number on your proxy card to vote at the meeting.

The meeting webcast will begin promptly at _____ Eastern Time. Diffusion encourages its stockholders to access the meeting prior to the start time. Online check-in will begin at _____ Eastern Time, and you should allow ample time for the check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please call the number on the virtual meeting portal landing page for assistance. For additional information on how you can attend and participate in the Diffusion special meeting, please see the instructions beginning on page 102 of the proxy statement/prospectus/information statement that follows.

The Diffusion board of directors has fixed _____, 2023 as the record date for the determination of Diffusion stockholders entitled to notice of, and to vote at, the Diffusion special meeting and any adjournment or postponement thereof. Only holders of record of shares of Diffusion Common Stock at the close of business on the record date are entitled to notice of, and to vote at, the Diffusion special meeting. At the close of business on the record date, Diffusion had _____ shares of Diffusion Common Stock outstanding and entitled to vote.

Your vote is important. The affirmative vote of the holders of a majority of the shares of Diffusion Common Stock present in person or represented by proxy at the Diffusion special meeting and entitled to vote generally on the subject matter, presuming a quorum is present, is required for approval of the Stock Issuance Proposal and the Postponement Proposal. The affirmative vote of the holders of a majority of the Diffusion Common Stock outstanding on the record date for the Diffusion special meeting is required for the approval of the Reverse Split Proposal. No proposal is conditioned upon any other proposal.

Even if you plan to attend the Diffusion special meeting virtually, Diffusion requests that you sign and return the enclosed proxy card or vote by Internet or telephone to ensure that your shares will be represented at the Diffusion special meeting if you are unable to attend.

DIFFUSION'S BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS ADVISABLE TO, AND IN THE BEST INTERESTS OF, DIFFUSION AND ITS STOCKHOLDERS AND HAS APPROVED EACH SUCH PROPOSAL. DIFFUSION'S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT DIFFUSION'S STOCKHOLDERS VOTE "FOR" EACH SUCH PROPOSAL.

By Order of the Diffusion Board of Directors,

William Elder
General Counsel and Corporate Secretary
Charlottesville, Virginia

, 2023

ABOUT THIS DOCUMENT

This document, which forms part of a registration statement on Form S-4 filed with the U.S. Securities and Exchange Commission (the “SEC”) by Diffusion, constitutes a prospectus of Diffusion under the Securities Act of 1933, as amended (the “Securities Act”), with respect to the shares of Diffusion Common Stock to be issued pursuant to the Merger Agreement, between Diffusion and EIP, pursuant to the Merger. This document also constitutes a notice of a meeting and a proxy statement of Diffusion under Section 14(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), with respect to the Diffusion special meeting at which Diffusion stockholders will be asked to consider and vote on a proposal to approve the issuance of Diffusion Common Stock to the securityholders of EIP as well as to consider and vote on certain other proposals.

No one has been authorized to provide you with information that is different from that contained in this proxy statement/prospectus/information statement. This proxy statement/prospectus/information statement is dated as of the date set forth on the cover hereof. You should not assume that the information contained in this proxy statement/prospectus/information statement is accurate as of any date other than that date. Neither the mailing of this proxy statement/prospectus/information statement to EIP stockholders nor the issuance by Diffusion of Diffusion Common Stock in connection with the proposed Merger will create any implication to the contrary.

This proxy statement/prospectus/information statement does not constitute an offer to sell, or a solicitation of an offer to buy, any securities, or the solicitation of a proxy, in any jurisdiction in which or from any person to whom it is unlawful to make any such offer or solicitation in such jurisdiction.

Information contained in this proxy statement/prospectus/information statement regarding EIP and its business, operations, management and other matters has been provided by EIP and information contained in this proxy statement/prospectus/information statement regarding Diffusion and its business, operations, management and other matters has been provided by Diffusion.

REFERENCES TO ADDITIONAL INFORMATION

This proxy statement/prospectus/information statement incorporates important business and financial information about Diffusion that is not included in or delivered with this document. You may obtain this information without charge through the SEC website (www.sec.gov) or upon your written or oral request by contacting the Corporate Secretary of Diffusion Pharmaceuticals Inc., 300 Main Street, Suite 201, Charlottesville, Virginia 22902 or by calling (434) 220-0718.

To ensure timely delivery of these documents, any request should be made no later than , 2023 to receive them before the special meeting.

For additional details about where you can find information about Diffusion, please see the section titled “Where You Can Find More Information” in this proxy statement/prospectus/information statement.

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Presentation of Information

In this proxy statement/prospectus/information statement, unless the context requires otherwise:

- “*Altitude Trial*” means Diffusion’s Phase 1b clinical trial evaluating TSC in normal healthy volunteers subjected to incremental levels of physical exertion while exposed to hypoxic and hypobaric conditions, or “simulated altitude,” completed in April 2022;
- “CG” means Canaccord Genuity LLC, Diffusion’s financial advisor;
- “Code” means the Internal Revenue Code of 1986, as amended;
- “*combined company*” means following the Merger, Diffusion (as it may be renamed in the Merger) and its direct and indirect subsidiaries, including EIP;
- “*Dechert*” means Dechert LLP, counsel to Diffusion.
- “DGCL” means the Delaware General Corporation Law;
- “*Diffusion*” means Diffusion Pharmaceuticals Inc., a Delaware corporation;
- “*Diffusion Common Stock*” means the common stock, par value \$0.001, of Diffusion;
- “*Effective Time*” means the effective time of the Merger;
- “EIP” means EIP Pharma, Inc., a Delaware corporation;
- “*EIP Common Stock*” means shares of common stock, par value \$0.001, of EIP;
- “*EIP Convertible Notes*” means those certain (i) convertible promissory notes of EIP, dated as of December 4, 2021, and (ii) convertible promissory notes of EIP, dated as of December 10, 2021;
- “*EIP Preferred Stock*” means shares of each of EIP’s Series A-1 preferred stock, par value \$0.001, EIP’s Series A-2 preferred stock, par value \$0.001, and EIP’s Series B preferred stock, par value \$0.001;
- “*Exchange Act*” means the Securities Exchange Act of 1934, as amended;
- “FDA” means the U.S. Food and Drug Administration;
- “GAAP” means U.S. generally accepted accounting principles;
- “GBM” means glioblastoma multiforme brain cancer;
- “*ILD-DLCO Trial*” means Diffusion’s Phase 2a clinical trial evaluating TSC in patients with previously diagnosed ILD who have a baseline DLCO test result that is abnormal using DLCO as a surrogate measure of oxygen transfer efficiency, initiated in December 2021;
- “IRS” means the Internal Revenue Service;
- “*Merger*” means on the terms and subject to the conditions under the Merger Agreement, the merger of Dawn Merger Sub Inc., a wholly-owned subsidiary of Diffusion, with and into EIP, with EIP surviving the Merger as a wholly-owned subsidiary of the combined company;
- “*Merger Agreement*” means the Agreement and Plan of Merger, dated as of March 30, 2023, by and among Diffusion, EIP and Dawn Merger Sub Inc., a wholly-owned subsidiary of Diffusion;
- “*Merger Sub*” means Dawn Merger Sub Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Diffusion;
- “Mintz” means Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel to EIP.
- “Nasdaq” means The Nasdaq Stock Market LLC;
- “NIA” means the National Institutes of Health’s National Institute on Aging;
- “*Oxygenation Trials*” means collectively, the TCOM Trial, the Altitude Trial, and the ILD-DLCO Trial;

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- “*Reverse Split*” means the proposed reverse stock split of outstanding Diffusion Common Stock at a ratio within a range of one new share for not less than and not greater than shares outstanding, at any time prior to December 31, 2023, the implementation and timing of which shall be subject to the discretion of Diffusion’s board of directors and, if the Merger Agreement is still in effect at such time, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time;
- “*Sarbanes-Oxley Act*” means the Sarbanes-Oxley Act of 2002, as amended;
- “*SEC*” means the U.S. Securities and Exchange Commission;
- “*Securities Act*” means the Securities Act of 1933, as amended;
- “*TCOM*” means transcutaneous oxygen measurement.
- “*TCOM Trials*” means Diffusion’s Phase 1b clinical trial evaluating the effects of TSC on peripheral tissue oxygenation in healthy normal volunteers using a TCOM device, completed in March 2021; and
- “*TSC*” means trans sodium crocetinate.

QUESTIONS AND ANSWERS ABOUT DIFFUSION'S SPECIAL STOCKHOLDER MEETING AND THE MERGER

Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed Reverse Split of Diffusion Common Stock described in the Reverse Split Proposal in this proxy statement/prospectus/information statement.

The following section provides answers to frequently asked questions about the special meeting of Diffusion's stockholders and the Merger. These questions and answers may not address all issues that may be important to you as a Diffusion or an EIP stockholder. For a more complete response to these questions and for additional information, please refer to the cross-referenced pages below. You should carefully read this entire proxy statement/prospectus/information statement, including each of the annexes.

Q: What is the Merger?

A: Diffusion, EIP and Merger Sub entered into the Merger Agreement on March 30, 2023. Pursuant to the Merger Agreement, and upon the terms and subject to the conditions set forth in the Merger Agreement, EIP will become a wholly-owned subsidiary of Diffusion. See "*The Merger Agreement*" beginning on page 146. The Merger will become effective at the time the Certificate of Merger has been duly filed with the Secretary of State of the State of Delaware (the "Effective Time"). At the Effective Time, Diffusion will be renamed "CervoMed Inc." and, subject to satisfying Nasdaq's initial listing standards, expects to trade on the Nasdaq Capital Market under the symbol "CRVO."

Immediately prior to the Effective Time, the EIP Convertible Notes and the EIP Preferred Stock will be converted into shares of EIP Common Stock. At the Effective Time, other than certain excluded shares and dissenting shares, each share of EIP Common Stock will be converted into the right to receive shares of Diffusion Common Stock, or the "Exchange Ratio" (as defined in the Merger Agreement). As of the date of the Merger Agreement, it was estimated that, after giving effect to the transactions contemplated thereby, the Exchange Ratio would be 0.1860 pre-split shares of Diffusion's Common Stock for each share of EIP Common Stock. In connection with and immediately prior to the consummation of the Merger, and subject to obtaining the requisite stockholder approval for the Reverse Split Proposal pursuant to this proxy statement/prospectus/information statement, Diffusion may effect a reverse stock split of outstanding Diffusion Common Stock, within a range of one new share for not less than and not greater than shares outstanding, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time, as discussed in this proxy statement/prospectus/information statement. Accordingly, on a post-reverse split basis, the Exchange Ratio would be within a range of approximately to post-split shares of Diffusion Common Stock, holding all other assumptions used in calculating the Exchange Ratio described elsewhere herein the same. The Exchange Ratio is determined pursuant to a formula in the Merger Agreement and described in this proxy statement/prospectus/information statement, and these estimates are subject to adjustment, as described below.

In connection with the Merger, each outstanding and unexercised option to purchase shares of EIP Common Stock will be assumed by Diffusion and will be converted into an option to purchase that number of shares of Diffusion Common Stock as determined pursuant to the Exchange Ratio. Diffusion stockholders and option holders will continue to own and hold their existing shares of Diffusion Common Stock and options, respectively. All options and warrants to purchase shares of Diffusion Common Stock that are outstanding immediately prior to the Effective Time will remain outstanding following the Effective Time.

Applying the Exchange Ratio, immediately after the Effective Time, former EIP equity holders immediately before the Merger are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and the Diffusion stockholders immediately before the Merger are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, subject to certain assumptions, including that net cash (as calculated in accordance with the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million. These estimates are subject to adjustment prior to the closing of the Merger, including an upward adjustment to the extent that Diffusion's net cash at the Effective Time is less than \$13.5 million (and as a result, Diffusion securityholders could own less, and EIP equity holders could own more, of the combined company), or a downward adjustment to the extent that Diffusion's net cash at the Effective Time is more than \$14.5 million (and as a result, Diffusion securityholders could own more, and EIP equity holders could own less, of the combined company). For example, if Diffusion's net cash at the Effective Time is \$13.5 million, applying the Exchange Ratio, the former EIP equity holders immediately before the Merger would own approximately 77.51% of the outstanding shares of Diffusion Common Stock following the Merger, and the Diffusion stockholders immediately before the Merger would own approximately 22.49% of the outstanding shares of Diffusion Common Stock following the Merger. If Diffusion's net cash at the Effective Time is \$15.0 million, applying the Exchange Ratio, the former EIP equity holders immediately before the Merger would own approximately 77.01% of the outstanding shares of Diffusion Common Stock following the Merger, and the Diffusion stockholders immediately before the Merger would own approximately 22.99% of the outstanding shares of Diffusion Common Stock following the Merger.

The Merger Agreement terms applicable to the calculation of the Exchange Ratio are complex and circumstances as of the Effective Time of the Merger may result in an Exchange Ratio that differs from estimates in this proxy statement/prospectus/information statement. See “The Merger Agreement — Merger Consideration and Exchange Ratio” beginning on page 146.

Q: What will happen to Diffusion if, for any reason, the Merger does not close?

A: If, for any reason, the Merger does not close, Diffusion’s board of directors may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the various assets of Diffusion or continue to operate the business of Diffusion. Diffusion may be unable to identify and complete an alternative strategic transaction or continue to operate the business due to limited cash availability, and it may be required to dissolve and liquidate its assets. In such case, Diffusion would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to its stockholders after paying the debts and other obligations of Diffusion and setting aside funds for reserves.

Q: Why is Diffusion proposing to merge with EIP?

A: Diffusion believes that the combined company will have several potential advantages, including:

- the combined company would possess sufficient resources, or have access to sufficient resources, to allow the management team to focus primarily on its plans for the continued development of EIP’s product pipeline, in particular, the advancement of oral stress kinase inhibitors, including EIP’s lead drug candidate neflamapimod, which is currently being developed for the treatment of DLB, including the possibility that the combined company would be able to take advantage of the potential benefits resulting from the combination of Diffusion’s SEC registration and Nasdaq listing with EIP’s business to raise additional funds in the future;
- the strength of the balance sheet of the combined company, which would include the cash that Diffusion currently holds, plus potential access to an additional \$21.0 million in funding from EIP’s grant from the NIA; and
- the combined company is expected to be led by an experienced senior management team and board of directors.

For a more complete discussion of Diffusion’s and EIP’s reasons for the Merger, please see the sections titled “*The Merger — Diffusion Reasons for the Merger*” and “*The Merger — EIP Reasons for the Merger*” beginning on pages 119 and 122, respectively.

Q: Why am I receiving this proxy statement/prospectus/information statement?

A: You are receiving this proxy statement/prospectus/information statement because you have been identified as a common stockholder of Diffusion as of the record date, or a stockholder of EIP eligible to execute the EIP written consent. If you are a common stockholder of Diffusion, you are eligible to vote at the Diffusion special stockholder meeting to approve, among other things, the Stock Issuance Proposal and the Reverse Split Proposal. If you are a stockholder of EIP, you are requested to sign and return the EIP written consent to adopt the Merger Agreement and approve the Merger and the other transactions contemplated thereby. This document serves as:

- a proxy statement of Diffusion used to solicit proxies for its special meeting of stockholders;
- a prospectus of Diffusion used to issue shares of Diffusion Common Stock in exchange for shares of EIP Common Stock in the Merger; and
- an information statement of EIP used to solicit the written consent of its stockholders for the adoption of the Merger Agreement and the approval of the Merger and related transactions.

Q: What is required to consummate the Merger?

A: To consummate the Merger, Diffusion stockholders must approve the Stock Issuance Proposal and the Reverse Split Proposal. In addition, EIP stockholders must adopt the Merger Agreement and approve the Merger and the transactions contemplated thereby.

Diffusion Stockholder Approval

The approval of the issuance of Diffusion Common Stock pursuant to the Merger Agreement by the stockholders of Diffusion requires the affirmative vote of the holders of a majority of the shares of Diffusion Common Stock present in person or represented by proxy at the Diffusion special meeting and entitled to vote generally on the subject matter, presuming a quorum is present at the meeting. The approval of the Reverse Split Proposal requires the affirmative vote of the holders of a majority of the Diffusion Common Stock outstanding on the record date for the Diffusion special stockholder meeting.

Diffusion's current directors and executive officers who collectively own or control an aggregate of less than 1.0% of the outstanding shares of Diffusion Common Stock are parties to support agreements with EIP (the "Diffusion Support Agreements"). The Diffusion Support Agreement provides that, among other things, each of the stockholders signatory thereto has agreed to vote or cause to be voted all of the shares of Diffusion Common Stock beneficially owned by such stockholder in favor of the matters to be brought before Diffusion's stockholders at the Diffusion special stockholder meeting. For a more detailed discussion of the Diffusion Support Agreements see the section titled "*Agreements Related to the Merger — Support Agreements and Written Consent*" beginning on page 166.

EIP Stockholder Approval

The adoption of the Merger Agreement and the approval of the Merger and transactions contemplated thereby by the stockholders of EIP requires the affirmative vote of both (1) the holders of a majority of the outstanding shares of EIP Preferred Stock and (2) the holders of a majority of the shares of EIP Common Stock (including the shares of EIP Preferred Stock, voting as a single class on an as-converted basis).

Certain EIP stockholders who in the aggregate own shares of EIP capital stock necessary to approve the Merger and related transactions contemplated by the Merger Agreement are parties to support agreements with Diffusion (the "EIP Support Agreements"). The EIP Support Agreements provide that, among other things, each of the stockholders signatory thereto has agreed to vote or cause to be voted all of the shares of EIP capital stock beneficially owned by such stockholder in favor of the Merger Agreement, the Merger and the other transactions contemplated thereby. For a more detailed discussion of the EIP Support Agreements see the section titled "*Agreements Related to the Merger — Support Agreements and Written Consent*" beginning on page 166.

Satisfaction of Other Closing Conditions

In addition to the requirement of obtaining such stockholder approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

For a more complete description of the closing conditions under the Merger Agreement, please see the section titled "*The Merger Agreement — Conditions to the Closing of the Merger*" beginning on page 150.

Q: What will Diffusion stockholders and option holders receive in the Merger?

A: At the Effective Time, Diffusion stockholders and option holders will continue to own and hold their existing shares or options to purchase shares of Diffusion Common Stock, subject to adjustment for the Reverse Split.

For a more complete description of what Diffusion stockholders will receive in the Merger, please see the sections titled "*Market Price and Dividend Information*" beginning on page 35 and "*The Merger Agreement — Merger Consideration and Exchange Ratio*" beginning on page 146.

Q: What will EIP stockholders, option holders and warrant holders receive in the Merger?

A: Each share of EIP capital stock outstanding will be converted into the right to receive a number of shares of Diffusion Common Stock calculated using the Exchange Ratio. Diffusion will assume outstanding and unexercised options to purchase shares of EIP capital stock, and in connection with the Merger such options will be converted into options to purchase shares of Diffusion Common Stock, with the number of Diffusion shares subject to such option and the exercise price being appropriately adjusted to reflect the Exchange Ratio. Each outstanding and unexercised warrant to purchase EIP Common Stock immediately prior to the Effective Time will be converted into and become a warrant to purchase shares of Diffusion Common Stock, adjusted to reflect the Exchange Ratio and treated in accordance with the terms thereof.

For a more complete description of what EIP stockholders, option holders and warrant holders will receive in the Merger, please see the sections titled “*Market Price and Dividend Information*” beginning on page 35 and “*The Merger Agreement — Merger Consideration and Exchange Ratio*” beginning on page 146.

Q: Who will be the directors of the combined company following the Merger?

A: Diffusion and EIP have agreed that, effective at the Effective Time, the board of directors of the combined company will consist of seven directors, comprised of five directors designated by EIP and two directors designated by Diffusion (until each of their respective successors are duly elected or appointed and qualified or their earlier death, resignation or removal). Sylvie Grégoire, PharmD, the current Executive Chair of EIP, is expected to serve as Chair of the board of directors for the combined company following the Effective Time. The other members of the combined company’s board of directors are expected to consist of Jeff Poulton, Jane Hollingsworth, JD, Frank Zavrl, Marwan Sabbagh, MD, John Alam, MD and Robert J. Cobuzzi, Jr., Ph.D. Ms. Hollingsworth currently serves as the Chair of Diffusion’s board of directors and Dr. Cobuzzi currently serves as President and Chief Executive Officer of Diffusion, in addition to being a member of Diffusion’s board of directors. Drs. Grégoire, Alam and Sabbagh and Messrs. Poulton and Zavrl each currently serve on EIP’s board of directors. See section titled “*Management Following the Merger — Executive Officers and Directors of the Combined Company Following the Merger*” beginning on page 247.

Q: Who will be the executive officers of combined company immediately following the Merger?

A: Following the Effective Time, the combined company is expected to be led by a management team composed of a combination of Diffusion’s and EIP’s current management teams, including: Dr. Alam, EIP’s current Chief Executive Officer, as Chief Executive Officer; Dr. Cobuzzi, Diffusion’s current Chief Executive Officer, as Chief Operating Officer; William Tanner, Ph.D., EIP’s current Chief Financial Officer, as Chief Financial Officer; Kelly Blackburn, MHA, EIP’s current Senior Vice President, Clinical Development, as Senior Vice President, Clinical Development; and William Elder, Diffusion’s current General Counsel and Corporate Secretary, as General Counsel and Corporate Secretary. See section titled “*Management Following the Merger — Executive Officers and Directors of the Combined Company Following the Merger*” beginning on page 247.

Q: What are the intended U.S. federal income tax consequences of the Merger to EIP United States stockholders?

A: Subject to the limitations and qualifications described in the section titled “*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*” of this proxy statement/prospectus/information statement, in the opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel to EIP, the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the “Code”). Assuming such treatment, and subject to the qualifications and limitations set forth in the section titled “*The Merger—Certain Material U.S. Federal Income Tax Consequences of the Merger*,” the material tax consequences to U.S. Holders (as defined herein) of EIP Common Stock are expected to be as follows:

- Each holder of EIP Common Stock will not recognize gain or loss upon the exchange of EIP Common Stock for Diffusion Common Stock pursuant to the Merger, except to the extent of cash received in lieu of a fractional share of Diffusion Common Stock as described below; and
- Each holder of EIP Common Stock generally will recognize gain or loss to the extent any cash received in lieu of a fractional share of Diffusion Common Stock exceeds or is less than the basis of such fractional share.

However, there are many requirements that must be satisfied in order for the Merger to be treated as a reorganization under Section 368(a) of the Code, some of which are based upon factual determinations, and the reorganization treatment could be affected by actions taken after the Merger. If the Merger failed to qualify as a reorganization under Section 368(a) of the Code, the EIP stockholders generally would recognize the full amount of gains and losses realized on the exchange of their EIP Common Stock in the Merger.

Tax matters are very complicated, and the tax consequences of the Merger to a particular EIP stockholder will depend on such stockholder's circumstances. Accordingly, you should consult your tax advisor for a full understanding of the tax consequences of the Merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws. For more information, please see the section titled "*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*" beginning on page 139.

Q: Do persons involved in the Merger have interests that may conflict with mine as a Diffusion stockholder?

A: Yes. In considering the recommendation of Diffusion's board of directors with respect to issuing shares of Diffusion Common Stock pursuant to the Merger Agreement and the other matters to be acted upon by Diffusion stockholders at the Diffusion special stockholder meeting, Diffusion stockholders should be aware that certain members of the Diffusion board of directors and executive officers of Diffusion have interests in the Merger that may be different from, or in addition to, interests they have as Diffusion stockholders.

For example, the employment agreements of Diffusion's executive officers provide for post-employment compensation arrangements. These Diffusion employment agreements establish the amount of severance payments and benefits available in the event of a termination of employment by Diffusion without other than for "cause", death or "disability," or upon the executive's resignation for "good reason" (as such terms are defined in the agreement).

Additionally, pursuant to the terms of the Merger Agreement, certain directors and executive officers of Diffusion will continue as directors and executive officers, respectively, of the combined company after the Effective Time and will be eligible for certain compensation as directors and executive officers.

As of May 5, 2023, the directors and executive officers of Diffusion owned, in the aggregate, approximately 0.2% of the outstanding voting shares of Diffusion Common Stock. In connection with the Merger, each of Diffusion's executive officers and directors have entered into support agreements, and Diffusion's directors and executive officers who beneficially hold less than 1% of outstanding shares of Diffusion's capital stock have entered into lock-up agreements. The support agreements and lock-up agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger — Support Agreements and Written Consent*" beginning on page 166.

Diffusion's board of directors was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement. For more information, please see the section titled "*The Merger — Interests of the Diffusion Directors and Executive Officers in the Merger*" beginning on page 133.

Q: Do persons involved in the Merger have interests that may conflict with mine as an EIP stockholder?

A: Yes. In considering the recommendation of the EIP's board of directors with respect to the adoption of the Merger Agreement and approving the Merger and transactions contemplated thereby by written consent, EIP stockholders should be aware that certain members of the EIP board of directors and executive officers of EIP have interests in the Merger that may be different from, or in addition to, interests they have as EIP stockholders. Certain EIP's executive officers have options to purchase shares of EIP Common Stock which will vest and convert into options to purchase a number of shares of Diffusion Common Stock determined by the Exchange Ratio, rounding any resulting fractional shares down to the nearest whole share, certain of EIP's directors and executive officers are expected to become directors and executive officers of the combined company upon the Effective Time and all of EIP's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. For more information, please see the section titled "*The Merger — Interests of the EIP Directors and Executive Officers in the Merger*" beginning on page 134.

Q: As a Diffusion stockholder, how does the Diffusion board of directors recommend that I vote?

A: After careful consideration, the Diffusion board of directors unanimously recommends that Diffusion stockholders vote:

- **“FOR”** the Stock Issuance Proposal;
- **“FOR”** the Reverse Split Proposal; and
- **“FOR”** the Postponement Proposal.

No stockholder proposal is conditioned upon any other stockholder proposal.

Q: As an EIP stockholder, how does EIP’s board of directors recommend that I vote?

A: After careful consideration, EIP’s board of directors recommends that the EIP stockholders execute the written consent indicating their votes in favor of the adoption of the Merger Agreement and the approval of the Merger and the transactions contemplated thereby.

Q: What risks should I consider as a Diffusion stockholder in deciding whether to vote in favor of the issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement or as an EIP stockholder to execute and return the written consent adopting the Merger Agreement and approval of the Merger and related transactions?

A: You should carefully review this proxy statement/prospectus/information statement, including the section titled “Risk Factors” beginning on page 36, which sets forth certain risks and uncertainties related to the Merger, risks and uncertainties to which the combined company’s business will be subject, and risks and uncertainties to which each of Diffusion and EIP, as an independent company, is subject.

Q: When do you expect the Merger to be consummated?

A: The Merger is anticipated to close as soon as possible after the Diffusion special stockholder meeting is held, which is currently scheduled for , 2023, but Diffusion cannot predict the exact timing of the closing. For more information, please see the section titled “*The Merger Agreement – Conditions to the Closing of the Merger*” beginning on page 150.

Q: What do I need to do now?

A: Diffusion and EIP urge you to read this proxy statement/prospectus/information statement carefully, including its annexes, and to consider how the Merger affects you.

If you are a Diffusion stockholder, you may provide your proxy instructions in one of two different ways. First, you can mail your signed proxy card or voting instruction form in the enclosed return envelope. Second, you may also provide your proxy instructions via the Internet or telephone by following the instructions on your proxy card or voting instruction form. Please provide your proxy instructions only once, unless you are revoking a previously delivered proxy instruction, and as soon as possible so that your shares can be voted at the special meeting of Diffusion stockholders.

If you are an EIP stockholder, you may execute and return your written consent to EIP in accordance with the instructions provided once this Registration Statement is declared effective by the SEC.

Q: As a holder of Diffusion Common Stock, what happens if I do not return a proxy card or otherwise provide proxy instructions, as applicable?

A: If you are a holder of record of Diffusion Common Stock and you return a signed proxy card without marking any selections, your shares will be voted **“FOR”** each of the Stock Issuance Proposal, the Reverse Split Proposal and the Postponement Proposal.

If you do not give instruction to your broker, your broker can vote your Diffusion shares with respect to “routine” items but not with respect to “non-routine” items, and, as a result, absent specific instructions from the beneficial owner of such shares, brokers are not empowered to vote those shares, referred to generally as “broker non-votes.” Broker non-votes, if any, will be treated as shares that are present at the Diffusion special meeting for purposes of determining whether a quorum exists but will not have any effect for the purpose of voting on Proposal No. 1 (Stock Issuance Proposal) and Proposal No. 3 (Postponement Proposal). Broker non-votes, if any, will have the same effect as “AGAINST” votes for Proposal No. 2 (Reverse Stock Split Proposal).

If your shares are held in “street name,” you should instruct your broker to vote your shares following the procedures provided by your broker to make sure your vote is counted.

Q: When and where will the special meeting of stockholders of Diffusion be held?

A: The special meeting of stockholders of Diffusion will be on , 2023, at , Eastern Time. The special meeting will be a completely virtual meeting of stockholders conducted exclusively by live audio webcast to enable Diffusion’s stockholders to participate from any location around the world that is convenient to them. No physical meeting will be held. Diffusion has created and implemented the virtual format to facilitate stockholder attendance and participation by enabling stockholders to participate fully, and equally, from any location around the world, at no cost. A virtual special meeting makes it possible for more stockholders (regardless of size, resources, or physical location) to have direct access to information more quickly, while saving the Diffusion and its stockholders time and money, especially as physical attendance at meetings has dwindled. Diffusion also believes that the online tools it has selected will increase stockholder communication. However, stockholders will bear any costs associated with its Internet access, such as usage charges from Internet access providers and telephone companies.

The online meeting will begin promptly at Eastern Time on , 2023. Diffusion encourages its stockholders to access the meeting approximately 15 minutes prior to the start time in order to leave ample time for the check-in. Please follow the registration instructions as outlined in this proxy statement/prospectus/information.

Q: How does a Diffusion stockholder attend the special meeting of stockholders of Diffusion be held? Does a Diffusion stockholder need to register in advance in order to attend the special meeting of stockholders of Diffusion?

A: Both Diffusion stockholders of record and street name Diffusion stockholders will be able to attend the special meeting of stockholders of Diffusion via live audio webcast and vote their shares electronically at the special meeting. **However, Diffusion stockholders will need to register in advance in accordance with the instructions below in order to attend.**

In order to attend the special meeting of stockholders of Diffusion, Diffusion stockholders must pre-register at by Eastern Time on , 2023. If a Diffusion stockholder holds their shares in “street name” through a bank, broker or other nominee, and also wishes to vote at the meeting, you will need to obtain from that entity a “legal proxy” and submit it when you register. After you register, you will receive an email with a unique link and password that will allow you to attend the meeting. If your shares are held in “street name” and you provided a legal proxy when you registered, that email will also contain a control number that will allow you to vote at the meeting. If you hold your shares through our transfer agent, use the control number on your proxy card to vote at the meeting. You will not need the control number to join the meeting, you will need it if you choose to vote during the meeting.

Q: How does a Diffusion stockholder submit questions for the special meeting of stockholders of Diffusion?

A: Diffusion stockholders can submit questions pertinent to meeting matters at the virtual special meeting of stockholders of Diffusion only if they are a stockholder of record Diffusion at the close of business on the record date or if they were a beneficial owner as of the record date and they are registered in advance to attend the special meeting. During the special meeting, Diffusion is committed to acknowledging each appropriate question in the order in which it was received. Diffusion stockholders may also submit questions prior to the date of the special meeting by e-mailing them to proxyrequests@diffusionpharma.com. When submitting questions, Diffusion stockholders should identify themselves and provide contact information in the event follow up is necessary. Each Diffusion stockholder who submits a question will be identified before his or her question is answered. Any questions relevant to the business of the Diffusion special meeting that cannot be answered due to time constraints can be submitted to Diffusion Investor Relations by e-mailing info@diffusionpharma.com. Diffusion stockholders participating in the virtual meeting will be in a listen-only mode and will not be able to speak during the webcast.

In accordance with the rules of order, a copy of which will be available during the special meeting, only questions pertinent to meeting matters will be answered. In the interest of fairness to all stockholders, the question and answer period will be limited to a total of twenty minutes and multiple questions submitted on the same topic will be summarized and responded to collectively. Diffusion reserves the right to not address any questions that are repetitious, irrelevant to Diffusion's business, related to pending or threatened litigation, derogatory in nature, related to personal grievances, or otherwise inappropriate.

Q: Whom does a Diffusion stockholder contact if he or she is encountering difficulties attending the special meeting of stockholders of Diffusion online?

A: There will be technicians ready to assist Diffusion stockholders with any technical difficulties they may have accessing the special meeting of stockholders of Diffusion live audio webcast. Please be sure to check in by Eastern Time on , 2023 (i.e., 15 minutes prior to the start of the meeting is recommended) so that any technical difficulties may be addressed before the special meeting live audio webcast begins. If a Diffusion stockholder encounters any difficulties accessing the webcast during the check-in or meeting time, please email or call .

Q: If my Diffusion shares are held in "street name" by my broker, will my broker vote my shares for me?

A: Unless your broker has discretionary authority to vote on certain matters, your broker will not be able to vote your shares of Diffusion Common Stock on matters requiring discretionary authority without instructions from you. Brokers are not expected to have discretionary authority to vote for the Stock Issuance Proposal, the Reverse Split Proposal or the Postponement Proposal. To make sure that your vote is counted, you should instruct your broker to vote your shares, following the procedures provided by your broker.

Q: May I change my vote after I have submitted a proxy or provided proxy instructions?

A: Diffusion stockholders of record, other than those Diffusion stockholders who are parties to support agreements, may change their vote at any time before their proxy is voted at the Diffusion special meeting in one of three ways. First, a Diffusion stockholder of record can send a timely written notice to the General Counsel & Corporate Secretary of Diffusion stating that it would like to revoke its proxy. Second, a Diffusion stockholder of record can submit another proper proxy with a more recent date than that of the proxy first given by following the Internet or telephone voting instructions or completing, signing, dating and returning a proxy card to Diffusion. Third, a Diffusion stockholder of record can attend the Diffusion special meeting and vote virtually. Attendance alone will not revoke a proxy. If a Diffusion stockholder of record or a stockholder who owns Diffusion shares in "street name" has instructed a broker to vote its shares of Diffusion Common Stock, the stockholder must follow directions received from its broker to change those instructions.

Q: Who is paying for this proxy solicitation?

A: Diffusion will pay for the costs of printing and filing this proxy statement/prospectus/information statement and proxy card. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Diffusion Common Stock for the forwarding of solicitation materials to the beneficial owners of Diffusion Common Stock. Diffusion will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. Diffusion has engaged Alliance Advisors, LLC to assist in the solicitation of proxies and provide related advice and informational support, for a services fee, and the reimbursement of customary disbursements, which are not expected to exceed \$ in total. In accordance with the Merger Agreement, a portion of these costs will be added to Diffusion's net cash calculation as an adjustment in the Diffusion stockholder's favor.

Q: Who can help answer my questions?

A: If you are a Diffusion stockholder and would like additional copies, without charge, of this proxy statement/prospectus/information statement or if you have questions about the Merger, including the procedures for voting your shares, you should contact Diffusion's proxy solicitor:

Alliance Advisors LLC

If you are an EIP stockholder and would like additional copies, without charge, of this proxy statement/prospectus/information statement or if you have questions about the Merger, including the procedures for voting your shares, you should contact:

EIP Pharma, Inc.
20 Park Plaza, Suite 424
Boston, MA 02116 USA
Attn: William Tanner (wtanner@eippharma.com)

PROSPECTUS SUMMARY

This summary highlights selected information from this proxy statement/prospectus/information statement and may not contain all of the information that is important to you. To better understand the Merger, the proposals being considered at the Diffusion special meeting and the EIP stockholder actions that are the subject of the written consent, you should read this entire proxy statement/prospectus/information statement carefully, including the Merger Agreement and the other annexes to which you are referred to herein. For more information, please see the section titled “Where You Can Find More Information” beginning on page 298.

The Parties

Diffusion Pharmaceuticals Inc.

300 Main Street, Suite 201
Charlottesville, Virginia 22902
(434) 220-0718

Diffusion is a biopharmaceutical company that has historically focused on developing novel therapies that may enhance the body’s ability to deliver oxygen to areas where it is needed most. Diffusion’s most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, most recently as an adjuvant treatment to standard of care therapy for GBM and other hypoxic solid tumors. In connection with the proposed merger with EIP, and pending its conclusion, Diffusion previously paused the initiation of the previously announced Phase 2 study of TSC in newly diagnosed GBM patients and will continue to attempt to identify sale or out-licensing transactions.

Dawn Merger Sub Inc.

300 Main Street, Suite 201
Charlottesville, Virginia 22902
(434) 220-0718

Merger Sub is a wholly-owned subsidiary of Diffusion and was formed solely for the purposes of carrying out the Merger.

EIP Pharma Inc.

20 Park Plaza, Suite 424
Boston, Massachusetts 02116
(617) 744-4400

EIP is a privately held, clinical stage CNS therapeutics company that is developing treatments for neurodegenerative diseases, such as DLB and other neurologic indications. EIP’s novel approach focuses on reducing the impact of inflammation in the brain, which is a key factor in the manifestation of neurodegenerative disease. In DLB, EIP believes that it is an industry-leader, as EIP is the only company of which EIP is aware with an asset that, in that disease, has shown statistically significant positive effects in a Phase 2a clinical trial and is about to enter late-stage (Phase 2b) clinical evaluation. Chronic activation of the enzyme, p38 mitogen-activated protein kinase (“MAPK”) alpha (“p38 α ”) in the neurons (nerve cells) within the brains of people with neurodegenerative diseases is believed to impair how neurons communicate through synapses (the connections between neurons). This impairment, termed synaptic dysfunction, leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in neuronal loss that leads to devastating disabilities, institutionalization and, ultimately, death. EIP believes that inhibiting p38 α in the brain, by interfering with key pathogenic drivers of disease, has the potential to improve cognitive and motor function observed in early-stage neurodegenerative diseases.

EIP is developing an oral therapy, neflamapimod, that penetrates the blood-brain barrier and inhibits activity of p38 α in the neuron. Based on preclinical and clinical work to date, EIP believes that if neflamapimod is given in the early stages of neurodegenerative diseases, it may reverse synaptic dysfunction and improve neuron health. In preclinical studies, neflamapimod has been shown to reverse the neurodegenerative process in the basal forebrain cholinergic system, the specific region of the brain that is the site of the major pathology in DLB. EIP obtained positive Phase 2a clinical data in DLB, and Phase 2 clinical data in AD provides supportive clinical data by demonstrating blood-brain-barrier penetration, target engagement, and identifying dose-response.

The Merger

On March 30, 2023, Diffusion entered into the Merger Agreement with EIP and Merger Sub. Pursuant to the Merger Agreement, and upon the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will merge with and into EIP, with EIP surviving as a wholly-owned subsidiary of Diffusion. At the Effective Time, Diffusion will be renamed “CervoMed Inc.” and, subject to satisfying Nasdaq’s initial listing standards, expects to trade on the Nasdaq Capital Market under the symbol “CRVO.”

At the Effective Time, each issued and outstanding share of EIP Common Stock (including shares of EIP Preferred Stock that will have been converted into EIP Common Stock immediately prior to the Effective Time) will be canceled and automatically converted into the right to receive a number of shares of Diffusion Common Stock based on the Exchange Ratio, which is subject to adjustment based on Diffusion’s net cash immediately prior to the Closing, and, to the extent implemented, the Reverse Split. Because Diffusion’s net cash balance will not be determined until immediately prior to the Closing, and because the number of shares of Diffusion Common Stock issuable to EIP equity holders is determined based on Diffusion’s net cash balance immediately prior to Closing, EIP equity holders cannot be certain of the exact number of shares of Diffusion Common Stock that will be issued to EIP equity holders when Diffusion stockholders vote on the proposals at the Diffusion special meeting of stockholders. This Exchange Ratio is an estimate only and the final Exchange Ratio will be determined pursuant to a formula described in more detail in the Merger Agreement and in this proxy statement/prospectus/information statement. Under the Exchange Ratio formula in the Merger Agreement, immediately following the Effective Time, former EIP equity holders are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and equity holders of Diffusion are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, in each case, subject to certain assumptions, including that net cash (as calculated in accordance with the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million. These estimates are subject to adjustment prior to the Effective Time, including an upward adjustment to the extent that Diffusion’s net cash at the Effective Time is less than \$13.5 million (and as a result, Diffusion securityholders could own less, and EIP equity holders could own more, of the combined company), or a downward adjustment to the extent that Diffusion’s net cash at the Effective Time is more than \$14.5 million (and as a result, Diffusion securityholders could own more, and EIP equity holders could own less, of the combined company).

Reasons for the Merger

In reaching its decision to approve entering into the Merger Agreement and recommending the approval of the issuance of shares of Diffusion Common Stock in the Merger by the Diffusion stockholders, Diffusion’s board of directors consulted with management and Diffusion’s financial and legal advisors and considered a variety of factors, including among others, the following (which are not in any relative order of importance and all of which Diffusion’s board of directors viewed as supporting its decision to approve the proposed transactions with EIP):

- the historical and current information concerning Diffusion’s business, financial performance, financial condition, including Diffusion’s cash position, operations, management and competitive position, the prospects of Diffusion and its lead product candidate, TSC, the nature of the biotechnology industry generally, including financial projections of Diffusion under various scenarios and its short- and long-term strategic objectives and the related risks and the belief that the combination of Diffusion’s and EIP’s businesses would create more value for Diffusion stockholders in the long-term than Diffusion could create as an independent, stand-alone company;
- that Diffusion’s board of directors and its financial and legal advisors undertook a comprehensive and thorough process of reviewing and analyzing potential strategic transactions to identify the opportunity that would, in the Diffusion board of directors’ opinion, create the most value for Diffusion’s stockholders, including the acquisition of new assets or companies, in-licensing and sales, remaining a standalone company pursuing a limited pipeline focusing on TSC and preclinical programs, reverse mergers, as well as a liquidation of Diffusion and the distribution to its stockholders of its remaining cash after the payment of or setting aside for the payment of Diffusion’s obligations in a liquidation scenario;

- the Diffusion board of directors' belief, based in part on the judgment, advice and analysis of Diffusion management with respect to the potential strategic, financial and operational benefits of the Merger (which judgment, advice and analysis was informed in part by the business, technical, financial, accounting, intellectual property and legal due diligence investigation performed by Diffusion with respect to EIP), that the Merger is more favorable to Diffusion's stockholders than the potential value that might have resulted from other strategic options available to Diffusion;
- the Diffusion board of directors' review with the management of Diffusion the current development plans of EIP's lead product candidate neflamapimod to confirm the likelihood that the combined company would possess sufficient resources, or have access to sufficient resources, to allow the management team to focus on its plans for the continued development of EIP's product pipeline, including the possibility that the combined company would be able to take advantage of the potential benefits resulting from the combination of Diffusion's SEC registration and Nasdaq listing with EIP's business to raise additional funds in the future;
- the strength of the balance sheet of the combined company, which would include the cash that Diffusion currently holds, plus potential access to an additional \$21.0 million in funding from EIP's grant awarded by the NIA;
- the benefits that Diffusion and its advisors were able to obtain during its negotiations with EIP, including the favorable additions to the calculation of Diffusion's net cash for purposes of calculating the Exchange Ratio and generally improving the contract terms relating to transaction certainty, and the Diffusion board of directors' belief that there was no assurance that a more favorable strategic opportunity would arise later or through any alternative transaction, and the terms and consideration reflected in the Merger Agreement was the best transaction that could be obtained by Diffusion stockholders from EIP at the time;
- that the combined company is expected to be led by an experienced senior management team and a board of directors with representation from each of the current boards of directors of Diffusion and EIP;
- the financial analysis completed by Diffusion management;
- the oral opinion of CG rendered to Diffusion's board of directors on March 29, 2023 (which was subsequently confirmed in writing by delivery of CG's written opinion dated March 29, 2023), to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written opinion, the Exchange Ratio pursuant to the Merger Agreement was fair, from a financial point of view, to Diffusion; and
- the Diffusion board of directors' belief that the Merger would provide existing Diffusion stockholders a significant opportunity to participate in the potential growth of the combined company following the Merger;
- that Diffusion's board of directors reviewed and considered the terms of the Merger Agreement, including the parties' respective representations, warranties and covenants, and the conditions to their respective obligations to consummate the Merger, the issuance of shares of Diffusion Common Stock and the other transactions contemplated by the Merger Agreement. See the section titled "*The Merger Agreement*" beginning on page 146 for a detailed discussion of the terms and conditions of the Merger Agreement; and
- that, in the view of Diffusion's board of directors, the \$765,000 termination fee that could become payable by Diffusion pursuant to the Merger Agreement was reasonable, would likely not deter alternative acquisition proposals and would likely not be required to be paid unless Diffusion's board of directors entered into an agreement providing for a transaction that would be more favorable to the Diffusion stockholders than the transactions contemplated by the Merger Agreement.

In the course of its deliberations, Diffusion's board of directors also considered a variety of risks and other countervailing factors related to the Merger and other transactions contemplated by the Merger Agreement, including among others:

- the fact that Diffusion stockholders will be sharing participation of Diffusion's upside with EIP stockholders as part of the combined company;

- the substantial expenses to be incurred in connection with the Merger and the other transactions contemplated by the Merger Agreement;
- the fact that projections of future results of operations and synergies are estimates based on assumptions that may not be realized within the expected time frame or at all;
- the possible volatility, at least in the short term, of the trading price of Diffusion Common Stock resulting from the announcement of the Merger Agreement;
- the risk that the Merger might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the Merger Agreement or on the delay or failure to complete the transactions contemplated by the Merger Agreement on Diffusion's financial position;
- the terms of the Merger Agreement, including covenants relating to (1) the two companies' conduct of their respective businesses during the period between the signing of the Merger Agreement and the completion of the Merger and the other transactions, including the requirement that the two companies' conduct business only in the ordinary course, subject to specific exceptions and (2) the restrictions on Diffusion's ability to solicit alternative transaction proposals;
- the fact that Diffusion may become obligated to pay EIP a termination fee of \$765,000 in certain circumstances as further discussed under the section titled "*The Merger Agreement*" beginning on page 146, which could potentially deter a potential acquirer from proposing an alternative transaction that may provide value to Diffusion stockholders superior to that of the proposed transactions;
- the potential for litigation relating to the proposed transactions and the associated costs, burden and inconvenience involved in defending those proceedings;
- the potential conflict of interest created by the fact that Diffusion's executive officers and directors have financial or other interests in the Merger that may be different from, or in addition to, those of other stockholders, as more fully described below in "*The Merger — Interests of the Diffusion Directors and Executive Officers in the Merger*"; and
- various other risks associated with the combined company and the merger, including those described in the sections titled "*Risk Factors*" beginning on page 36 and "*Cautionary Statement Concerning Forward-Looking Statements*" beginning on page 100.

For more information on the Diffusion board of director's reasons for the transaction, see the section titled "*The Merger—Diffusion Reasons for the Merger*" beginning on page 119.

In reaching its unanimous decision to approve the Merger Agreement and the related transactions, EIP's board of directors considered a number of factors, including, among others, the following:

- historical and current information concerning EIP's business, including its financial performance and condition, operations, management and competitive position;
- EIP's prospects if it were to remain an independent privately held company, including its need to obtain additional financing and the terms on which it would be able to obtain such financing, if at all;
- EIP's board of directors' belief that no alternatives to the Merger were reasonably likely to create greater value for EIP equity holders, after reviewing the various financing and other strategic options to enhance stockholder value that were considered by EIP's board of directors;
- the cash resources of the combined company expected to be available at the closing of the Merger and the anticipated burn rate of the combined organization;
- the broader range of investors to support the development of EIP's product candidates than it could otherwise obtain if it continued to operate as a privately held company;
- potential to provide its current stockholders with greater liquidity by owning stock in a public company;
- the expectation that the Merger with Diffusion would be a more time- and cost-effective means to access capital than other options considered;

- the expectation that substantially all of EIP’s employees, particularly its management, will serve in similar roles at the combined organization;
- the fact that shares of Diffusion Common Stock issued to EIP equity holders will be registered on a Form S-4 registration statement and will become freely tradable for EIP equity holders who are not affiliates of EIP and who are not parties to the Lock-Up Agreements;
- the support agreements pursuant to which certain directors and officers of Diffusion and certain directors, officers and stockholders of EIP have agreed, solely in their capacity as stockholders of Diffusion and EIP, respectively, to vote all of their shares of EIP capital stock or Diffusion Common Stock in favor of the adoption or approval, respectively, of the Merger Agreement;
- the ability to obtain a Nasdaq listing and comply with Nasdaq listing requirements;
- the terms and conditions of the Merger Agreement, including, without limitation, the following:
 - o the expected relative percentage ownership of EIP equity holders and Diffusion securityholders in the combined company initially at the Effective Time and the implied valuation of EIP based on Diffusion’s cash contribution to the combined company;
 - o the parties’ representations, warranties and covenants and the conditions to their respective obligations;
 - o the limited number and nature of the conditions of the obligation of Diffusion to consummate the Merger; and
 - o the likelihood that the Merger will be consummated on a timely basis.

For more information on EIP’s board of directors’ reasons for the transaction, see the section titled “*The Merger—EIP Reasons for the Merger*” beginning on page 122.

Opinion of Diffusion’s Financial Advisor

Diffusion engaged CG to provide financial advisory services and to assist the Diffusion board of directors in the consideration and evaluation of the Merger. At a meeting of the Diffusion board of directors held on March 29, 2023 to evaluate the Merger, CG delivered to the Diffusion board of directors an oral opinion, which opinion was confirmed by delivery of a written opinion, dated March 29, 2023, to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written opinion, the Exchange Ratio pursuant to the Merger Agreement was fair, from a financial point of view, to Diffusion. For purposes of its opinion, and at the direction and with the consent of the Diffusion board of directors, CG assumed that the Parent Net Cash (as defined in the Merger Agreement) will not be less than \$13.5 million nor more than \$14.5 million, and the Parent Allocation Percentage (as defined in the Merger Agreement) will be 0.2275 without adjustment. CG did not express any view on, and its opinion did not address, any other term or aspect of any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with the Merger.

The full text of CG’s written opinion is attached to this proxy statement/prospectus/information statement as *Annex C* and is incorporated into this proxy statement/prospectus/information statement by reference. The description of CG’s opinion set forth in this proxy statement/prospectus/information statement is qualified in its entirety by reference to the full text of such opinion. Diffusion stockholders are encouraged to read CG’s opinion carefully and in its entirety for a description of the procedures followed, assumptions made, matters considered and qualifications and limitations on the review undertaken by CG in connection with its opinion. CG’s opinion was addressed to the Diffusion board of directors, was only one of many factors considered by the Diffusion board of directors in its evaluation of the Merger and only addresses the fairness, from a financial point of view and as of the date of the opinion, to Diffusion of the Exchange Ratio pursuant to the Merger Agreement. CG’s opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to Diffusion, nor does it address the underlying business decision of Diffusion to proceed with the Merger or any view on any other term or aspect of the Merger. CG’s opinion was solely directed to and for the information of the Diffusion board of directors (in its capacity as such) in connection with its evaluation of the Merger and does not constitute advice or a recommendation to the Diffusion board of directors, any stockholder of Diffusion, or any other person as to how the Diffusion board of directors or such stockholder or other person should vote with respect to the Merger or otherwise act on any other matter relating to the Merger. Subsequent developments may affect the conclusions expressed in CG’s opinion if such opinion were rendered as of a later date, and CG disclaims any obligation to advise any person of any change in any manner affecting its opinion that may come to CG’s attention after the date of its opinion. CG has assumed no responsibility for updating, revising or reaffirming its opinion based on circumstances or events occurring after the date of the opinion.

See Annex C and the section of this proxy statement/prospectus/information statement entitled “*The Merger—Opinion of Diffusion’s Financial Advisor*” beginning on page C-1.

Overview of the Merger Agreement and Agreements Related to the Merger Agreement

Merger Consideration

At the Effective Time, each outstanding share of EIP Common Stock outstanding immediately prior to the Effective Time (other than certain excluded shares and dissenting shares, as described below) will be converted solely into the right to receive a number of shares of Diffusion Common Stock equal to the Exchange Ratio.

Each share of EIP capital stock (other than EIP Common Stock) and each share of EIP capital stock held in the treasury of EIP or owned, directly or indirectly, by Diffusion, Merger Sub or any subsidiary of EIP, immediately prior to the Effective Time will automatically be cancelled and will cease to exist, and no consideration will be delivered in exchange therefor. These shares are excluded from the receipt of consideration in the Merger. In addition, shares of the EIP capital stock (other than the excluded shares) that are outstanding immediately prior to the Effective Time and held by a holder who is entitled to demand and has properly demanded appraisal for such shares of EIP capital stock in accordance with Section 262 of the Delaware General Corporation Law will not be converted into or be exchangeable for the right to receive a portion of the Merger consideration unless and until such holder fails to perfect or withdraws or otherwise loses such holder’s right to appraisal and payment under the DGCL.

Under the Merger Agreement, the outstanding shares of EIP Preferred Stock are required to be converted prior to the Effective Time into the applicable number of shares of EIP Common Stock. In addition, the outstanding EIP Convertible Notes are required to be converted into shares of EIP Common Stock at or prior to the Effective Time and treated consistent with the other shares of EIP Common Stock.

The Merger Agreement does not include a price-based termination right. Accordingly, the market value of the shares of Diffusion Common Stock issued pursuant to the Merger will depend on the market value of the shares of Diffusion Common Stock at the time the Merger closes and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement.

Treatment of EIP Stock Options and Warrants

Stock Options

Diffusion will assume the EIP Pharma, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan (the “EIP Plan”), and all rights with respect to each outstanding option to purchase EIP Common Stock in accordance with its terms and the terms of the stock option agreement by which such option is evidenced. Accordingly, at the Effective Time, each outstanding EIP option (“EIP Option”) will be assumed by Diffusion and converted into an option to purchase, on the same terms and conditions, a number of shares of Diffusion Common Stock determined by multiplying (1) the number of shares of EIP Common Stock that were subject to such option, as in effect immediately prior to the Effective Time, by (2) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Diffusion Common Stock, at an exercise price per share determined by dividing (A) the per share exercise price of EIP Common Stock subject to such option, as in effect immediately prior to the effective time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent.

Warrants

At the Effective Time, all EIP warrants outstanding immediately prior to the Merger will be assumed by Diffusion and become exercisable (1) for a number of shares of Diffusion Common Stock equal to the number of shares of EIP Common Stock subject to such warrant immediately prior to the effectiveness of the Merger multiplied by the Exchange Ratio (rounding down to the nearest whole share) and (2) at an exercise price per share of Diffusion Common Stock equal to the exercise price per share of EIP Common Stock applicable immediately prior to the effectiveness of the Merger divided by the Exchange Ratio (rounding up to the nearest whole cent).

Conditions to the Closing of the Merger

Each party's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the closing of the Merger, of various conditions, which include stockholder approvals as set forth below:

- the holders of EIP capital stock shall have adopted and approved the Merger Agreement, the Merger and the transactions contemplated by the Merger Agreement by the requisite vote in accordance with EIP's organizational documents and the Delaware General Corporation Law; and
- the holders of Diffusion Common Stock shall have approved issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement and, if applicable, the Reverse Split by the requisite vote in accordance with EIP's organizational documents and the Delaware General Corporation Law.

In addition to obtaining such stockholder approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

Non-Solicitation

Each of Diffusion and EIP agreed that during the period commencing on the date of the Merger Agreement and ending on the earlier of the consummation of the Merger or the termination of the Merger Agreement, except as described below, Diffusion and EIP will not, nor will either party authorize any of the directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors or representatives retained by it to, directly or indirectly:

- solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any "acquisition proposal" or "acquisition inquiry" (each as defined below) or take any action that could reasonably be expected to lead to an acquisition proposal or acquisition inquiry;
- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or acquisition inquiry;
- engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;
- approve, endorse or recommend an acquisition proposal; or
- execute or enter into any letter of intent or similar document or any contract providing for any acquisition proposal.

Neither Diffusion's board of directors nor any committee thereof may change its recommendation in favor of the Merger, except that prior to receipt by Diffusion of its stockholder approval, Diffusion's board of directors may effect a change in recommendation if:

- An intervening event has occurred, or Diffusion's board of directors shall have received an acquisition proposal and determined in good faith, and after consultation with outside legal counsel, that such acquisition proposal is a superior proposal and that the failure to effect such a change in recommendation would constitute a violation of the board's fiduciary duties under applicable law;
- Diffusion has provided at least four business days' prior written notice to EIP of Diffusion's intent to effect a change in recommendation and the specific reasons therefor, which notice shall include the identity of the person making such superior proposal, and has caused its financial advisors and outside legal counsel to negotiate with EIP in good faith to make such adjustments to the terms and conditions so that the acquisition proposal ceases to constitute a superior offer; and
- After EIP shall have delivered to Diffusion a written offer to alter the terms or conditions of the Merger Agreement during the four-business day period referred to above, Diffusion's board of directors shall have determined in good faith (based on the advice of its outside legal counsel), that the failure to effect a change in recommendation would constitute a violation of its fiduciary duties under applicable law.

In the event of any material amendment to any superior offer, Diffusion would be required to provide EIP with notice of such material amendment and there would be a new two business day period following such notification during which the parties would be obligated to comply again with the requirements described above.

If EIP receives an acquisition proposal or acquisition inquiry at any time during the period between March 30, 2023, and earlier to occur of (a) the Effective Time and (b) termination of the Merger Agreement, then EIP must promptly, and in no event later than one business day after becoming aware of such acquisition proposal or acquisition inquiry, advise Diffusion orally and in writing of such acquisition proposal or acquisition inquiry, including the identity of the person making or submitting the acquisition proposal or acquisition inquiry and the material terms thereof. EIP must keep Diffusion reasonably informed with respect to the status and material terms of any such acquisition proposal or acquisition inquiry and any material modification or proposed material modification thereto.

For a more complete description of the non-solicitation provisions, please see the section titled “*The Merger Agreement—Non-Solicitation*” beginning on page 155.

Termination of the Merger Agreement

The Merger Agreement may be terminated at any time before the Effective Time, whether before or after the required stockholder approvals in connection with the transactions have been obtained, in accordance with the provisions and in the circumstance provided in the Merger Agreement. For a more complete description of the termination provisions, please see the section titled “*The Merger Agreement—Termination*” beginning on page 162.

Termination Fees

If the Merger Agreement is terminated under certain circumstances and certain other events occur, Diffusion will be required to pay to EIP a nonrefundable fee in an amount equal to \$765,000. Moreover, if Diffusion fails to pay when due any amount payable by it pursuant to the Merger Agreement, and in order to obtain such payment EIP commences a suit that results in a judgment against Diffusion for such payment, then Diffusion will be required to pay interest on and reasonable fees and expenses incurred in connection with the collection of such overdue amount in addition to the \$765,000 termination fee. For a more complete description of the termination provisions and termination fees, please see the section titled “*The Merger Agreement—Termination Fees*” beginning on page 164.

Support Agreements and Written Consent

EIP

Concurrently with the execution of the Merger Agreement and as a condition and inducement to Diffusion’s willingness to enter into the Merger Agreement, the directors, executive officers and certain principal stockholders of EIP, in their capacity as stockholders of EIP, entered into support agreements with Diffusion, pursuant to which, among other things, such stockholders agreed, solely in their capacity as an EIP stockholder, to vote all of their shares of EIP capital stock in favor of the adoption of the Merger Agreement and approval of the Merger and related transactions and to acknowledge that the adoption of the Merger Agreement and approval of the Merger and related transactions is irrevocable. In addition, these EIP stockholders agreed not to, directly or indirectly, knowingly take any action that EIP is not permitted to take under the non-solicitation provisions of the Merger Agreement. The EIP stockholders that are party to a support agreement with Diffusion hold a sufficient number of shares of EIP capital stock to adopt the Merger Agreement and approve the Merger and related transactions. Following the effectiveness of the registration statement of which this proxy statement/prospectus/information statement is a part, such holders will execute written consents to adopt the Merger Agreement and approve the Merger and related transactions.

Diffusion

Concurrently with the execution of the Merger Agreement and as a condition and inducement to EIP’s willingness to enter into the Merger Agreement, the directors and executive officers of Diffusion, in their capacity as Diffusion stockholders, entered into a support agreement with EIP pursuant to which, among other things, such stockholders agreed, solely in their capacity as a stockholder, to vote all of their shares of Diffusion Common Stock in favor of the approval of the issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement. In addition, these Diffusion stockholders agreed not to, directly or indirectly, knowingly take any action that Diffusion is not permitted to take under the non-solicitation provisions of the Merger Agreement. The stockholders of Diffusion that are party to a support agreement with EIP consist of Diffusion’s current directors and executive officers who collectively beneficially own or control an aggregate of less than 1% of the outstanding shares of Diffusion Common Stock.

Lock-up Agreements

EIP

As a condition to the closing of the Merger, EIP's directors, executive officers and certain principal stockholders, who beneficially hold 69.3% of EIP Common Stock on an as-converted to common stock basis, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company's common stock for up to 180 days following the Effective Time, other than in the case of the lock-up agreements entered into with John Alam, MD, Sylvie Grégoire, PharmD, and two trusts affiliated with Drs. Alam and Grégoire, which will be subject to a 12-month lockup.

Diffusion

As a condition to the closing of the Merger, Diffusion's directors and executive officers, who beneficially hold less than 1% of outstanding shares of Diffusion's capital stock, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company's common stock for 180 days following the Effective Time.

Management Following the Merger

Following the Effective Time, the combined company's directors and executive officers are expected to be composed of members of the following current Diffusion and EIP boards of directors and management teams:

Name	Position(s)
Directors	
Sylvie Grégoire, PharmD.	Chair of the Board of Directors
John Alam, M.D.	Director
Robert J. Cobuzzi, Jr., Ph.D.	Director
Jane Hollingsworth, J.D.	Director
Jeff Poulton	Director
Marwan Sabbagh, M.D.	Director
Frank Zavrl	Director
Executive Officers	
John Alam, MD	Chief Executive Officer
Robert J. Cobuzzi, Jr., Ph.D.	Chief Operating Officer
William Tanner, Ph.D.	Chief Financial Officer
Kelly Blackburn, MHA	Senior Vice President, Clinical Development
William Elder	General Counsel and Corporate Secretary

The Diffusion Special Meeting

The special meeting of stockholders of Diffusion will be held virtually on _____, 2023 at _____, Eastern Time by means of a live webcast for the following purposes:

- to consider and vote on a proposal to approve, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), (A) the issuance of shares of Diffusion Common Stock pursuant to the Merger, which will represent more than 20% of the shares of Diffusion Common Stock outstanding immediately prior to the Merger, and (B) the change of control resulting from the Merger, or the Stock Issuance Proposal;

- to consider and vote on a proposal to approve an amendment to the certificate of incorporation of Diffusion, as amended, the form of which is attached as *Annex B* to this proxy statement/prospectus/information statement, to effect the “Reverse Split of Diffusion Common Stock at a ratio within a range of one new share for not less than and not greater than shares outstanding, at any time prior to December 31, 2023, the implementation and timing of which shall be subject to the discretion of Diffusion’s board of directors and, if the Merger Agreement is still in effect at such time, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time, or the Reverse Split Proposal; and
- To consider and vote on a proposal to approve a postponement or adjournment of the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposals set forth above, or the Postponement Proposal.

Collectively the proposals above are referred to as the Diffusion Proposals. On each matter to be voted upon, stockholders have one vote for each share of Diffusion Common Stock owned as of _____, 2023. Votes will be counted by the inspector of election. The following table summarizes vote requirements and the effect of abstentions and broker non-votes.

Proposal Number	Proposal Description	Vote Required for Approval	Effect of Abstentions	Effect of Broker Non-Votes
1	Stock Issuance Proposal	FOR votes from the holders of a majority of shares present in person or represented by proxy at a meeting at which a quorum is present and entitled to vote generally on the subject matter	Against	None
2	Reverse Stock Proposal	FOR votes from the holders of a majority of outstanding shares	Against	Against
3	Postponement Proposal	FOR votes from the holders of a majority of shares present in person or represented by proxy at a meeting at which a quorum is present and entitled to vote generally on the subject matter	Against	None

No Diffusion Proposal is conditioned upon any other Diffusion Proposal.

EIP Solicitation of Written Consents

The adoption of the Merger Agreement and the approval of the Merger and related transactions by the EIP stockholders requires the affirmative vote of both (1) the holders of a majority of the outstanding shares of EIP Preferred Stock and (2) the holders of a majority of the shares of EIP Common Stock (including the shares of EIP Preferred Stock, voting as a single class on an as-converted basis).

The EIP stockholders who are party to the support agreements have agreed to, among other things, execute an action by written consent in favor of the Merger Agreement, the Merger and the other transactions contemplated thereby. These stockholders own a sufficient number of shares of EIP capital stock to adopt the Merger Agreement. No meeting of EIP stockholders to vote for the Merger Agreement, the Merger and the other transactions contemplated thereby will be held; however, all EIP stockholders will have the opportunity to execute a written consent in favor of the Merger Agreement, the Merger and the other transactions contemplated thereby.

In addition to the requirement of obtaining such stockholder approval and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

Interests of Directors and Executive Officers of Diffusion and EIP

Interests of the Diffusion Directors and Executive Officers in the Merger

In considering the recommendation of Diffusion’s board of directors with respect to the issuance of shares of Diffusion Common Stock as contemplated by the Merger Agreement and the other matters to be acted upon by Diffusion stockholders at the Diffusion special meeting, Diffusion stockholders should be aware that certain members of Diffusion’s board of directors and executive officers of Diffusion have interests in the Merger that may be different from, or in addition to, interests they have as Diffusion stockholders.

Certain of Diffusion's existing directors and executive officers are expected to remain directors and executive officers, respectively, of the combined company. As of May 5, 2023, Diffusion directors and executive officers held 4,458 shares of outstanding Diffusion Common Stock in the aggregate, vested Diffusion stock options covering 49,019 shares of Diffusion Common Stock and 1,343 restricted stock unit awards. Diffusion's directors and executive officers have entered into support agreements in connection with the Merger.

However, the Merger will not constitute a change of control event that would otherwise trigger payment of severance or potential acceleration of equity awards to any of Diffusion's named executive officers in connection with the closing of the Merger.

For more information, please see the sections titled "*The Merger — Interests of the Diffusion Directors and Executive Officers in the Merger*" beginning on page 270 and "*Certain Relationships and Related-Party Transactions—Diffusion*" beginning on page 133.

Interests of the EIP Directors and Executive Officers in the Merger

In considering the recommendation of EIP's board of directors with respect to approving the Merger and related transactions by written consent, EIP stockholders should be aware that certain members of EIP's board of directors and certain executive officers of EIP have interests in the Merger that may be different from, or in addition to, interests they have as EIP stockholders. For example, certain of EIP's directors and executive officers have options, subject to vesting, to purchase shares of EIP Common Stock which, at Closing, shall be converted into and become options to purchase shares of Diffusion Common Stock. Further, EIP's directors and executive officers are expected to become directors and executive officers of Diffusion upon the Closing, and all of EIP's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement.

As of April 1, 2023, EIP directors and executive officers held 209,102 shares of EIP Common Stock in the aggregate, 13,512,835 shares of EIP Preferred Stock in the aggregate (convertible into EIP Common Stock at the Closing on a one-for-one basis), vested EIP stock options covering 396,250 shares of EIP Common Stock and EIP Convertible Notes convertible into 1,850,417 shares of EIP Common Stock at the Closing. EIP's directors and executive officers have entered into support agreements in connection with the Merger.

The support agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger—Support Agreements and Written Consent*" in this proxy statement/prospectus/information statement.

For more information, please see the sections titled "*The Merger — Interests of the EIP Directors and Executive Officers in the Merger*" beginning on page 134 and "*Certain Relationships and Related-Party Transactions—EIP*" beginning on page 270.

Considerations with Respect to U.S. Federal Income Tax Consequences of the Merger

Subject to the limitations and qualifications described in the section titled "*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*" of this proxy statement/prospectus/information statement, in the opinion of Mintz, counsel to EIP, the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code. Assuming such treatment and subject to the qualifications and limitations set forth in the section titled "*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*," the material tax consequences to U.S. Holders (as defined herein) of EIP Common Stock are expected to be as follows:

- a holder of EIP Common Stock will not recognize gain or loss upon the exchange of EIP Common Stock for Diffusion Common Stock pursuant to the Merger, except to the extent of cash received in lieu of a fractional share of Diffusion Common Stock as described below;
- a holder of EIP Common Stock who receives cash in lieu of a fractional share of Diffusion Common Stock in the Merger generally will recognize capital gain or loss in an amount equal to the difference between the amount of cash received instead of a fractional share and the stockholder's tax basis allocable to such fractional share;

- the aggregate tax basis for the shares of Diffusion Common Stock that a holder of EIP Common Stock receives in the Merger will equal the stockholder's aggregate tax basis in the shares of EIP Common Stock surrendered upon the closing of the Merger, decreased by the amount of any tax basis allocable to a fractional share for which cash is received; and
- the holding period of the shares of Diffusion Common Stock received by a holder of EIP Common Stock in the Merger will include the holding period of the shares of EIP Common Stock surrendered in exchange therefor provided the surrendered EIP Common Stock is held as a capital asset (generally, property held for investment) at the time of the Merger.

Tax matters are very complicated, and the tax consequences of the Merger to a particular EIP stockholder will depend on such stockholder's circumstances. Accordingly, you should consult your tax advisor for a full understanding of the tax consequences of the Merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws. For more information, please see the section titled "*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*" beginning on page 139.

Summary of Risk Factors

Both Diffusion and EIP are subject to various risks associated with their businesses and their industries. In addition, the Merger, including the possibility that the Merger may not be completed, poses a number of risks to each company and its respective stockholders.

Risks Related to Diffusion

- Diffusion has not yet obtained regulatory approvals for any of its product candidates and, accordingly, generates no revenue from the sale of products currently. Any investment in Diffusion Common Stock is speculative and risky.
- Diffusion is heavily dependent on its employees. If any of Diffusion's employees terminate their employment, Diffusion may not be able to run its day-to-day operations or consummate the Merger.
- While seeking a partner to continue development of TSC, Diffusion may become involved in disputes with counterparties relating to the development TSC, which may be costly and time consuming for Diffusion. There can be no assurance that Diffusion will be able to monetize the TSC assets, which may have a material impact on its stock price.
- If the Merger does not close, Diffusion may decide to pursue a liquidation and dissolution and there can be no assurances as to the amount of available cash left, if any, to distribute to Diffusion stockholders.

Risks Related to EIP

- EIP currently does not have, and may never have, any products that generate significant revenues.
- EIP is heavily dependent on the success of its lead product candidate, neflamapimod, which is still under clinical development. If neflamapimod does not receive regulatory approval or is not successfully commercialized, EIP's business will be materially harmed.
- EIP has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability.
- EIP's reliance on third parties for the production of neflamapimod may result in delays in its clinical trials or regulatory approvals and may impair the development and ultimate commercialization of neflamapimod, which would adversely impact its business and financial position.
- Even if neflamapimod or any other product candidate that EIP develops receives marketing approval, it may fail to achieve the level of acceptance necessary for commercial success.
- If EIP does not adequately protect its proprietary rights, it may not be able to compete effectively.
- If EIP fails to comply with its obligations under its existing license agreement with Vertex Pharmaceuticals Incorporated ("Vertex"), or with any future intellectual property licenses with third parties, it could lose license rights that are important to its business.

Risks Related to the Merger and the Combined Company

- the Exchange Ratio is adjustable based on Diffusion's net cash at the closing of the Merger, so the consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed;
- a delay or failure to complete the Merger may result in Diffusion paying a termination fee and could harm the price of Diffusion Common Stock and Diffusion's future business and operations;
- if the Merger is not completed, Diffusion may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed transaction with EIP, or at all, and Diffusion may be unable to reestablish an operating business. Diffusion's board of directors may decide to pursue a dissolution and liquidation of Diffusion. In such an event, the amount of cash available for distribution to Diffusion's stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities;
- the issuance of shares of Diffusion Common Stock to EIP stockholders in the Merger will dilute substantially the voting power of Diffusion's current stockholders;
- the pendency of the Merger could have an adverse effect on the trading price of Diffusion Common Stock and Diffusion's business, financial condition, results of operations or business prospects;
- stockholder litigation and regulatory inquiries and investigations are expensive and could harm Diffusion's business, financial condition and operating results and could divert management attention;
- if Nasdaq does not approve Diffusion's listing application for the combined company and the parties waive the Nasdaq closing condition and continue with the Merger, Diffusion may be subject to delisting;
- the Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes;
- certain Diffusion and EIP executive officers and directors have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests;
- the market price of the combined company's common stock may decline as a result of the Merger;
- during the pendency of the Merger, Diffusion and EIP may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses;
- certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement;
- the lack of a public market for EIP shares makes it difficult to determine the fair market value of the EIP shares, and the stockholders of EIP may receive consideration in the Merger that is less than the fair market value of the EIP shares and/or Diffusion may pay more than the fair market value of the EIP shares;
- the long-range financial projections for EIP, which were considered by the Diffusion board of directors in evaluating the Merger and used by CG at the direction of the Diffusion board of directors in connection with its fairness opinion and related financial analyses, reflect numerous variables, estimates and assumptions and are inherently uncertain. If any of these variables, estimates and assumptions prove to be wrong, such as the assumptions relating to the approval of EIP's product candidates, the actual results for the combined company's business may be materially different from the results reflected in the long-range financial projections; and
- the unaudited pro forma condensed combined financial statements included in this proxy statement/prospectus/information statement are presented for illustrative purposes only and may not be an indication of the combined company's actual financial condition or results of operations of future periods, or the financial condition or results of operations that would have been realized following the completion of the Merger.

Diffusion and EIP both encourage you to carefully read and consider these risks and the other risks discussed in greater detail under the section titled “*Risk Factors*” beginning on page 36.

Regulatory Approvals

In the United States, Diffusion must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with the issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement and the filing of this proxy statement/prospectus/information statement with the SEC.

Nasdaq Stock Market Listing

Diffusion has agreed to use its commercially reasonable efforts (1) to maintain its existing listing on the Nasdaq Capital Market until the effective time of the Merger and obtain approval of the listing of the combined company on the Nasdaq Capital Market, (2) to prepare and submit a notification form for the listing of the shares of Diffusion Common Stock to be issued in the Merger and cause such shares to be approved for listing (subject to official notice of issuance), (3) to effect the Reverse Split (if necessary) and (4) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial Nasdaq Listing Application for the Diffusion Common Stock on the Nasdaq Capital Market and to cause such listing application to be conditionally approved prior to the effective time of the Merger. If the closing of the Merger occurs and the Nasdaq Listing Application is accepted, Diffusion anticipates that the common stock of the combined company will be listed on the Nasdaq Capital Market following the Effective Time under a new trading symbol “CRVO.”

Anticipated Accounting Treatment

The Merger will be treated by Diffusion as a reverse recapitalization in accordance with U.S. generally accepted accounting principles (“GAAP”). EIP has been determined to be the acquiring company in the Merger for financial reporting purposes based upon several factors, including: (i) former EIP securityholders are expected to own a substantial majority of the Diffusion Common Stock outstanding immediately following the Effective Time, (ii) EIP is entitled to designate the majority (five of seven) of initial members of the board of directors of the combined company, and (iii) EIP’s current senior management will hold the majority (three of five) positions in the senior management of the combined company. As a result of EIP being treated as the acquiring company for financial reporting purposes, if the Merger is consummated, among other things, the historical financial statements of EIP will become the historical consolidated financial statements of the combined company. See the “*Unaudited Pro Forma Condensed Combined Financial Information*” elsewhere in this proxy statement/prospectus/information statement for additional information.

Appraisal Rights and Dissenters’ Rights

Holders of shares of Diffusion capital stock are not entitled to appraisal rights in connection with the merger. EIP stockholders are entitled to appraisal rights in connection with the Merger under Delaware law. For more information about such rights, see the provisions of Section 262 of the Delaware General Corporation Law (the “DGCL”), attached hereto as *Annex D*, and the section titled “*The Merger — Appraisal Rights and Dissenters’ Rights*” beginning on page 142.

Comparison of Stockholder Rights

Both Diffusion and EIP are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the DGCL. If the Merger is completed, EIP stockholders will become Diffusion stockholders, and their rights will be governed by the DGCL, the bylaws of Diffusion, as amended, and the certificate of incorporation of Diffusion, as amended, as may be amended by the Reverse Split Proposal if approved by the Diffusion stockholders at the Diffusion special meeting. The rights of Diffusion stockholders contained in Diffusion’s certificate of incorporation, as amended, and bylaws, as amended, differ from the rights of EIP stockholders under EIP’s current certificate of incorporation and bylaws, as more fully described under the section titled “*Comparison of Rights of Holders of Diffusion Stock and EIP Stock*” beginning on page 284 of this proxy statement/prospectus/information statement.

MARKET PRICE AND DIVIDEND INFORMATION

Diffusion Common Stock is listed on the Nasdaq Capital Market under the symbol “DFFN.” EIP is a private company and its common stock is not publicly traded.

The closing price of Diffusion Common Stock on March 29, 2023, the trading day immediately prior to the public announcement of the merger on March 30, 2023, as reported on the Nasdaq Capital Market, was \$4.93 per share. The closing price of Diffusion Common Stock on May 5, 2023, as reported on the Nasdaq Capital Market, was \$3.81 per share.

Because the market price of Diffusion Common Stock is subject to fluctuation, the market value of the shares of Diffusion Common Stock that EIP stockholders will be entitled to receive in the Merger may increase or decrease.

Assuming the successful application for initial listing with the Nasdaq Capital Market, following the Effective Time, Diffusion expects the combined company’s common stock will be listed on the Nasdaq Capital Market and will trade under Diffusion’s new name, “CervoMed Inc.” and trading symbol “CRVO.”

As of _____, 2023, the record date for the Diffusion Special Meeting, there were approximately _____ stockholders of record.

Dividend Policy

Diffusion has never declared or paid any cash dividends on its common stock. Diffusion does not intend to pay cash dividends on Diffusion Common Stock for the foreseeable future.

EIP has never paid or declared any cash dividends on EIP capital stock. If the Merger does not occur, EIP does not anticipate paying any cash dividends on its capital stock in the foreseeable future, and EIP intends to retain all available funds and any future earnings to fund the development and expansion of its business.

Any future determination to pay dividends on shares of the combined company’s common stock will be at the discretion of its board of directors and will depend upon a number of factors, including its results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that its board of directors may deem relevant.

RISK FACTORS

The combined company will be faced with a market environment that cannot be predicted and that involves significant risks, many of which will be beyond its control. In addition to the other information contained in this proxy statement/prospectus/information statement, you should carefully consider the risks described below before making any investment decisions. In addition, you should read and consider the risks associated with the business of Diffusion because these risks may also affect EIP and the combined company. You should also read and consider the other information in this proxy statement/prospectus/information statement and the other documents incorporated by reference into this proxy statement/prospectus/information statement. Please see the section titled “Where You Can Find More Information” beginning on page 298.

Risks Related to the Merger

The Exchange Ratio is adjustable based on Diffusion’s net cash at the closing of the Merger but is not adjustable based on changes in the market value of Diffusion Common Stock following the date of the Merger Agreement and prior to the Closing, either of which could result in the value of the merger consideration having a greater or lesser value at the time of Closing than at the time the Merger Agreement was signed.

The relative proportion of the combined company that the Diffusion stockholders will own when the Merger closes will be based on the valuations of Diffusion and EIP and the Exchange Ratio as negotiated by the parties and as specified in the Merger Agreement. Under the Exchange Ratio formula described in the Merger Agreement, the equity holders of EIP immediately before the effective time of the Merger are expected to hold approximately 77.26% of the outstanding shares of Diffusion Common Stock immediately after the Effective Time and the equity holders of Diffusion immediately before the Effective Time are expected to hold approximately 22.74% of the outstanding shares of Diffusion Common Stock immediately after the effective time, in each case, assuming Diffusion’s net cash (as calculated pursuant to the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million.

Furthermore, any changes in the market price of Diffusion Common Stock before the completion of the Merger will not affect the number of shares of Diffusion Common Stock issuable to EIP’s equityholders pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of Diffusion Common Stock declines from the market price on the date of the Merger Agreement, then EIP equityholders could receive merger consideration with substantially lower market value than the value of such merger consideration on the date of the Merger Agreement. Conversely, if before the completion of the Merger the market price of Diffusion Common Stock increases from the market price of Diffusion Common Stock on the date of the Merger Agreement, then EIP’s equityholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement.

For more information, see the section titled “*The Merger Agreement — Merger Consideration and Exchange Ratio*” beginning on page 146.

Diffusion’s net cash may be less than \$13.5 million at the closing of the Merger, which would result in Diffusion’s stockholders owning a smaller percentage of the combined company than currently anticipated, and, if Diffusion’s net cash is less than \$12.0 million at the Determination Date (as defined in the Merger Agreement), could even cause a condition to EIP’s obligation to consummate the Merger fail to be satisfied and may result in the termination of the Merger Agreement.

For purposes of the Merger Agreement, net cash is subject to certain reductions, including, without limitation, accounts payable, accrued expenses (except those related to the Merger), current liabilities payable in cash, unpaid expenses related to the Merger and certain other unpaid obligations, including outstanding lease obligations. In the event the amount of Diffusion’s cash is smaller or such reductions are greater than anticipated, Diffusion stockholders could hold a significantly smaller portion of the combined organization. Diffusion is required to have net cash of at least \$12.0 million at the closing of the Merger as a condition to EIP’s obligation to consummate the Merger. In the event that Diffusion’s net cash falls below this threshold, a condition to the EIP’s obligation to consummate the Merger would not be satisfied and EIP would have the right to terminate the Merger Agreement if Diffusion were unable to cure such deficiency in accordance with the terms of the Merger Agreement and Diffusion’s net cash continues to be lower than \$12.0 million.

There is no assurance that the proposed Merger between Diffusion and EIP will be completed in a timely manner or at all.

Even if the proposals referred to herein are approved by the stockholders of Diffusion and EIP, specified other conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled “*The Merger Agreement — Conditions to Closing of the Merger*” beginning on page 150. Diffusion and EIP cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and Diffusion and EIP each may lose some or all of the intended benefits of the Merger.

A delay or failure to complete the Merger may result in Diffusion paying a termination fee and could harm the price of Diffusion Common Stock and Diffusion’s future business and operations.

If the Merger is not completed or is delayed, Diffusion’s business is subject to a number of additional and heightened risks, including, among others:

- Diffusion expects to continue to incur significant expenses while the Merger is pending;
- if the Merger Agreement is terminated under certain circumstances and certain events occur, Diffusion may be required to pay a termination fee of \$765,000. Moreover, if Diffusion fails to pay when due the termination fee, and in order to obtain such payment EIP commences a suit that results in a judgment against Diffusion for such payment, then it will be required to pay interest on and reasonable fees and expenses incurred in connection with the collection of such overdue amount in addition to the \$765,000 fee;
- one or more of Diffusion’s remaining employees may terminate their employment with Diffusion on short notice, which could potentially harm Diffusion’s ability to consummate the Merger, to run its day-to-day operations, as well as fulfill its reporting obligations as a public company;
- the price of Diffusion Common Stock may decline and remain volatile; and
- certain of the remaining costs related to the Merger, such as investment banking, legal and accounting fees, which Diffusion estimates will total approximately \$3.0 million, of which approximately \$0.5 million must be paid even if the Merger is not completed.

In addition, if the Merger Agreement is terminated and Diffusion’s or EIP’s board of directors determines to seek another business combination, there can be no assurance that either company will be able to diversify and enhance its product candidate portfolio on terms equivalent or more attractive than the Merger. Moreover, it will be difficult for Diffusion to continue development of TSC, since many development activities have been put on hold, and the employment of Diffusion’s Chief Medical Officer and of its Chief Regulatory Officer has been terminated.

If the Merger is not completed, Diffusion may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed transaction with EIP, or at all, and Diffusion may be unable to reestablish an operating business. Diffusion’s board of directors may decide to pursue a dissolution and liquidation of Diffusion. In such an event, the amount of cash available for distribution to Diffusion’s stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

Diffusion has paused significant portions of its TSC development activities, including initiation of its previously announced Phase 2 study of TSC in newly diagnosed GBM patients and have implemented operating cost reductions and organizational restructurings, including a reduction in its workforce, to preserve its cash resources. Diffusion’s strategic focus has shifted to the identification and evaluation of a range of potential strategic alternatives designed to maximize stockholder value.

To date, Diffusion’s current assets consist primarily of cash, cash equivalents and marketable securities, its clinical assets, its listing on the Nasdaq Capital Market and the Merger Agreement with EIP. The completion of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits Diffusion expects or enhance stockholder value.

If Diffusion is unable to consummate the Merger with EIP, Diffusion's board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed merger with EIP. Attempting to complete an alternative transaction will be costly and time consuming, and Diffusion can make no assurances that such an alternative transaction would occur at all. Alternatively, Diffusion's board of directors may elect to continue operations to conduct another study of TSC or decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution, if any, to Diffusion's stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as Diffusion continues to fund its operations. In addition, if Diffusion's board of directors was to approve and recommend, and its stockholders were to approve, a dissolution and liquidation of the company, Diffusion would be required under Delaware corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to its stockholders. Diffusion's commitments and contingent liabilities may include severance obligations, regulatory and clinical obligations remaining under its Phase 2 study of TSC, fees and expenses related to the Merger and liabilities relating to any investigations of, or litigation against, Diffusion and other various claims and legal actions. As a result of this requirement, a portion of Diffusion's assets may need to be reserved pending the resolution of such obligations. In addition, Diffusion may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, Diffusion's board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Diffusion Common Stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

The issuance of shares of Diffusion Common Stock to EIP stockholders in the Merger will dilute substantially the voting power of Diffusion's current stockholders.

The issuance of shares of Diffusion Common Stock to EIP stockholders in the Merger will reduce significantly the relative voting power of each share of Diffusion Common Stock held by Diffusion's current securityholders. Consequently, Diffusion securityholders as a group will have significantly less influence over the management and policies of the combined company after the Merger than prior to the Merger.

If the combined company after the Merger is unable to realize the strategic and financial benefits currently anticipated from the Merger, the Diffusion stockholders and the EIP stockholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving the expected commensurate benefit, or receiving only part of the commensurate benefit to the extent the combined company is able to realize only part of the expected strategic and financial benefits currently anticipated from the Merger.

The pendency of the Merger could have an adverse effect on Diffusion's business, financial condition, results of operations or business prospects.

The pendency of the Merger could disrupt Diffusion's business in the following ways, including among others:

- the attention of Diffusion's management may be directed toward the closing of the Merger and related matters and may be diverted from the day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with Diffusion as a result of the merger, whether pursuant to the terms of their existing agreements with Diffusion or otherwise.

Should they occur, any of these matters could harm Diffusion's financial condition, results of operations or business prospect.

Certain stockholders could attempt to influence changes within Diffusion which could adversely affect Diffusion's operations, financial condition and the value of Diffusion Common Stock.

One or more of Diffusion's stockholders may from time to time seek to acquire a significant or controlling stake in Diffusion, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes to Diffusion's board of directors or corporate governance policies. Campaigns by stockholders to effect changes at publicly traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, could disrupt Diffusion's operations and divert the attention of the Diffusion board of directors and senior management from the pursuit of the proposed Merger, and could adversely affect Diffusion's operations, financial condition, ability to consummate the Merger and the value of Diffusion Common Stock. For example, in November 2022, LifeSci Special Opportunities Master Fund Ltd. (the "LifeSci Fund"), a Diffusion stockholder, informed the Company of its intent to nominate an alternative slate of directors for election at Diffusion's 2022 annual meeting of stockholders, which was subsequently withdrawn following Diffusion and the LifeSci Fund entering into a settlement agreement on December 11, 2022.

The settlement agreement provides that, among other things, (1) the LifeSci Fund and its affiliates would immediately and irrevocably withdraw their nominees for election as directors of Diffusion at Diffusion's 2022 annual stockholder meeting and (2) subject to certain conditions, including the LifeSci Fund and its affiliates continuing to hold the same number of shares of Diffusion Common Stock and not breaching the terms of the settlement agreement, Diffusion will appoint one of the LifeSci Funds' nominees to Diffusion's board of directors in the future if Diffusion has not consummated any tender offer or exchange offer, merger, acquisition, business combination, reorganization, restructuring, recapitalization, sale or acquisition of material assets, or liquidation or dissolution by July 1, 2023.

On March 29, 2023, a representative of the LifeSci Fund delivered a letter to the Diffusion's board of directors which, among other things, urged Diffusion's board of directors to pursue a dissolution of Diffusion and distribution to stockholders of remaining cash in lieu of pursuing any strategic transaction alternative. Following instruction by Diffusion's board of directors, on March 31, 2023, Dechert, counsel for Diffusion, emailed the LifeSci Fund's outside counsel on Diffusion's behalf, informing the LifeSci Fund that Diffusion believes such actions violated the settlement agreement. Counsel for the LifeSci Fund replied that same day that LifeSci Fund understands and will comply with its obligation under the settlement agreement.

Despite these assurances, during a personal lunch meeting on April 13, 2023 unrelated to Diffusion and the Merger, a managing director of LifeSci Capital informed John Alam, the Chief Executive Officer of EIP, that Mr. Dobkin was speaking to other stockholders of Diffusion and that a number of Diffusion's stockholders intended to vote against the Merger and had agreed to vote against any future proposals that might be submitted for a vote of Diffusion stockholders. On April 20, 2023, Dechert sent a letter to the LifeSci Fund's outside counsel on Diffusion's behalf, notifying the LifeSci Fund that Mr. Dobkin's conversations with Diffusion's stockholders were in breach of the Settlement Agreement. On May 2, 2023, counsel for the LifeSci Fund replied refuting that the LifeSci Fund has breached the Settlement Agreement.

Stockholder litigation and regulatory inquiries and investigations are expensive and could harm Diffusion's business, financial condition and operating results and could divert management attention.

In the past, securities class action litigation and/or stockholder derivative litigation and inquiries or investigations by regulatory authorities have often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, such as the Merger, or the announcement of negative events, such as negative results from clinical trials. Diffusion is currently and may in the future be the target of this type of litigation as a result of changes in Diffusion's stock price, past transactions, results of clinical trials or other matters. Any stockholder litigation and/or regulatory investigations against Diffusion, whether or not resolved in Diffusion's favor, could result in substantial costs and divert Diffusion's management's attention from other business concerns, which could adversely affect Diffusion's business and cash resources and Diffusion's ability to consummate a potential strategic transaction or the ultimate value Diffusion's stockholders receive in any such transaction.

Diffusion or EIP may waive one or more of the conditions to the Merger without recirculation of this proxy statement/prospectus/information statement or resoliciting stockholder approval.

Conditions to Diffusion's or EIP's obligations to complete the Merger may be waived, in whole or in part, to the extent permitted by law, either unilaterally or by agreement of Diffusion, EIP and Merger Sub. In the event of a waiver of a condition, the Diffusion's board of directors will evaluate the materiality of any such waiver to determine whether amendment of this proxy statement/prospectus/information statement and resolicitation of stockholder approval is necessary. In the event that Diffusion's board of directors, in its own reasonable discretion, determines any such waiver is not significant enough to require recirculation of this proxy statement/prospectus/information statement and re-solicitation of its stockholders, it will have the discretion to complete the Merger without seeking further stockholder approval, which decision may have a material adverse effect on the Diffusion stockholders.

If Nasdaq does not approve Diffusion's listing application for the combined company and the parties waive the Nasdaq closing condition and continue with the Merger, Diffusion may be subject to delisting.

Diffusion has filed an initial listing application with Nasdaq pursuant to Nasdaq's "reverse merger" rules. In the event the application is not accepted by Nasdaq and the parties waive the Nasdaq closing condition and proceed with the Merger, the combined company will be subject to delisting proceedings and could be delisted. If Diffusion's shares lose their status on the Nasdaq Capital Market, Diffusion believes that its shares would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by OTC Markets Group Inc., such as the OTC Pink marketplace and now known as the OTCQB market. These markets are generally considered not to be as efficient as, and not as broad as, the Nasdaq Capital Market. If Diffusion's common stock is delisted, this would, among other things, substantially impair its ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for the combined company. Additionally, investors would find it more difficult to buy and sell shares of the combined company's common stock.

Diffusion or EIP may waive one or more of the conditions to the Merger without re-soliciting stockholder approval.

Certain conditions to Diffusion's and EIP's respective obligations to complete the Merger may be waived, in whole or in part, to the extent permitted by law and the Merger Agreement, either unilaterally or by agreement of Diffusion and EIP.

In the event of a waiver of a condition, the Diffusion board of directors will evaluate the materiality of any such waiver to determine whether amendment of this proxy statement/prospectus/information statement and re-solicitation of proxies is necessary. In the event that the Diffusion board of directors, in its own reasonable discretion, determines any such waiver is not significant enough to require re-solicitation of its stockholders, it will have the discretion to complete the Merger without seeking further stockholder approval, which decision may have a material adverse effect on the Diffusion stockholders. For example, if Diffusion and EIP agree to waive the requirement that the Nasdaq application be accepted for listing prior to the consummation of the Merger, and their respective boards of directors elected to proceed with the closing of the Merger, Nasdaq may notify the combined company of its determination to delist the company's securities based upon the failure to satisfy the initial inclusion criteria subject to a right of appeal by the combined company to stay the delisting action pending a Nasdaq hearings panel decision.

Notwithstanding the foregoing, certain closing conditions may not be waived due to applicable law or otherwise. The following closing conditions may not be waived: receipt of the requisite stockholder approvals by each party; the effectiveness of the registration statement of which this proxy statement/prospectus/information statement forms a part; and the absence of any order or injunction that has the effect of prohibiting the consummation of the Merger. The foregoing closing conditions are the only closing conditions to the Merger that may not be waived. All other closing conditions to the Merger may be waived by EIP and/or Diffusion, as applicable. See the section "*The Merger Agreement—Conditions to the Closing of the Merger*" beginning on page 150 for further information.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either Diffusion or EIP can refuse to complete the Merger if there is a material adverse change affecting the other party between the date of the Merger Agreement and the closing of the Merger. However, pursuant to the terms of the Merger Agreement, certain types of changes do not permit either party to refuse to complete the Merger, even though such change could have a material adverse effect on Diffusion or EIP, including:

- changes or conditions generally affecting the industries in which Diffusion, EIP or their respective subsidiaries operate, or the economy or the financial, debt, banking, capital, credit or securities markets, in the United States, including effects on such industries, economy or markets resulting from any regulatory and political conditions or developments in general;
- the outbreak or escalation of war or acts of terrorism or any natural disasters, acts of God or comparable events;

- any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or any worsening of such epidemic, pandemic or disease outbreak or any declaration of martial law, quarantine or similar directive, policy or guidance or law or other action by any governmental entity in response thereto;
- changes in applicable law or GAAP, or the interpretation or enforcement thereof after the date of the Merger Agreement;
- the public announcement of the Merger Agreement or the pendency of the Merger Agreement;
- any failure, in and of itself, by Diffusion or EIP to meet any internal or published projections, forecasts, estimates, or predictions in respect of revenues, earnings, or other financial or operating metrics for any period excluding any underlying effect that may have caused such failure;
- any change, in and of itself, in the market price or trading volume of Diffusion’s common stock or in Diffusion’s credit ratings excluding any underlying effect that may have caused such change; or
- any specific action taken (or omitted to be taken) by Diffusion, EIP or their respective subsidiaries at or with the express written direction or written consent of the other party (other than any such action or omission required by the Merger Agreement).

If one or more such adverse changes occur and Diffusion and EIP still complete the Merger, the combined company stock price may suffer. This in turn may reduce the value of the Merger to the stockholders of Diffusion and EIP.

Certain Diffusion and EIP executive officers and directors have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Certain officers and directors of Diffusion and EIP will participate in arrangements that provide them with interests in the Merger that are different from yours, including, among others, the continued service as officers and/or directors of the combined company, and continued indemnification. For more information, please see the sections titled “*The Merger — Interests of the Diffusion Directors and Executive Officers in the Merger*” beginning on page 133 and “*The Merger — Interests of the EIP Directors and Executive Officers in the Merger*” beginning on page 134.

The market price of the combined company’s common stock following the Merger may decline as a result of the Merger.

There can be no assurance as to the market price of the combined company’s common stock as a result of the Merger for a number of reasons. The market could decline including, including if:

- investors react negatively to the prospects of the combined company’s business and prospects from the Merger;
- the effect of the Merger on the combined company’s business and prospects is not consistent with the expectations of financial or industry analysts;
- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts; or
- the Reverse Split Proposal is viewed negatively by the market.

During the pendency of the Merger, Diffusion and EIP may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede the ability of Diffusion and EIP to make acquisitions, subject, in the case of Diffusion, to certain exceptions relating to fiduciary duties, or complete other transactions that are not in the ordinary course of business pending the closing of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets or other business combination outside the ordinary course of business, with any third-party, subject to, in the case of Diffusion, certain exceptions. Any such transactions could be favorable to such party’s stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of Diffusion and EIP from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except, with respect to Diffusion, in certain circumstances where Diffusion's board of directors determines in good faith, after consultation with its financial advisor and outside legal counsel, that an unsolicited alternative takeover proposal constitutes or could be reasonably likely to result in a superior takeover proposal. In addition, if Diffusion or EIP terminate the Merger Agreement under certain circumstances, including terminating because of a decision of a board of directors to recommend an alternative proposal, Diffusion may be required to pay a termination fee of \$765,000. These obligations could discourage third parties from submitting alternative takeover proposals to Diffusion and its stockholders and may cause the Diffusion board of directors to be less inclined to recommend an alternative proposal, even if any such third party were prepared to pay consideration with a higher value than the value of the Merger.

Because the lack of a public market for EIP's capital stock makes it difficult to evaluate the fairness of the Merger, the stockholders of EIP may receive consideration in the Merger that is less than the fair market value of EIP's capital stock and/or Diffusion may pay more than the fair market value of EIP's capital stock.

The outstanding capital stock of EIP is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of EIP's capital stock. Because the percentage of Diffusion equity to be issued to EIP stockholders was determined based on negotiations between the parties, it is possible that the value of the Diffusion Common Stock to be received by EIP stockholders will be less than the fair market value of EIP's capital stock, or Diffusion may pay more than the aggregate fair market value for EIP's capital stock.

The combined company will incur significant transaction costs as a result of the Merger, including investment banking, legal, and accounting fees. In addition, the combined company will incur significant operating expenses which cannot be accurately estimated at this time. Actual transaction costs may substantially exceed the parties' estimates and may have an adverse effect on the combined company's financial condition and operating results.

The long-range financial projections for EIP included in the section titled "The Merger — Certain Unaudited Long-Range Financial Projections of EIP's Business" beginning on page 131, which were considered by the Diffusion board of directors in evaluating the Merger and used by CG at the direction of the Diffusion board of directors in connection with its fairness opinion and related financial analyses, reflect numerous variables, estimates and assumptions and are inherently uncertain. If any of these variables, estimates and assumptions prove to be wrong, such as the assumptions relating to the approval of EIP's product candidates, the actual results for the combined company's business may be materially different from the results reflected in the long-range financial projections.

As further described below in the section titled "The Merger — Certain Unaudited Long-Range Financial Projections of EIP's Business", in connection with the Diffusion board of directors' evaluation of the Merger, preliminary internal financial projections for EIP were prepared by the management of EIP and provided to the management of Diffusion for, following certain adjustments, consideration by the Diffusion board of directors and use by Diffusion's financial advisor, CG, in connection with the rendering of its fairness opinion and performing its related financial analyses. The long-range financial projections reflect numerous variables, estimates, and assumptions made by EIP's management at the time the initial financial projections were prepared by EIP and Diffusion's management at the time such adjustments were made. If any of these variables, estimates and assumptions prove to be wrong, the actual results for the combined company's business may differ materially from the results reflected in the long-range financial projections.

The estimated probabilities of success included in the long-range financial projections take into account a range of potential outcomes, including outcomes in which product candidates fail to achieve commercial launch due to commercial and regulatory uncertainty (including failure to obtain regulatory authorization to market the applicable product candidate) as well as economic and portfolio management decisions and competition, and these assumptions, including those with respect to regulatory approval and probability of success more broadly, are inherently uncertain and could prove inaccurate. If one or more of the EIP product candidates do not receive marketing authorization when anticipated, for the indications anticipated, or at all, or the other assumptions reflected in the estimates as to probability or magnitude of success prove untrue, the actual results of the combined company's business will differ materially from the results reflected in the long-range financial projections. For example, while the long-range financial projections reflect the assumption that neflamapimod is approved for commercial sale in the U.S. by the FDA at a particular time in the future, if neflamapimod is not approved at such time or at all then actual results will differ materially, including the potential for neflamapimod to generate no revenue at all.

In addition, the long-range financial projections cover a significant period of time, specifically through 2036. This extended period was used in light of the anticipated timing for regulatory approval and the initiation of commercial sales of EIP's product candidates. However, the risks and uncertainties regarding the long-range financial projections, including the potential for adverse developments such as delays in obtaining or failure to obtain regulatory approvals or additional competition or changes in the competitive or regulatory landscape, increase with each successive year and the likelihood that the actual results will differ materially from the projected results increase with each successive year. The long-range financial projections also do not reflect potential changes in general business, economic, market and financial conditions and any changes in any of these conditions over the period of the projections could result in the actual results differing materially from the results reflected in the long-range financial projections.

The fairness opinion delivered by CG to Diffusion's board of directors prior to the entry into the Merger Agreement does not reflect changes in circumstances that may have occurred since the date of the opinion.

The Diffusion board of directors has not obtained an updated fairness opinion either as of the date of this proxy statement/prospectus/information statement or as of any other date subsequent to the date of such opinion from CG. Changes in circumstances, including in the operations and prospects of Diffusion or EIP, stock prices, general market and economic conditions and other factors, some or all of which may be beyond the control of Diffusion are not reflected in such opinion. The opinion does not speak as of any date other than the date of such opinion. CG has assumed no responsibility for updating, revising or reaffirming its opinion based on circumstances or events occurring after the date of such opinion.

Because the Merger will result in an ownership change under Section 382 of the Code for Diffusion, Diffusion's pre-merger net operating loss ("NOL") carryforwards and certain other tax attributes will be subject to limitation. In addition, the NOL carryforwards and other tax attributes of EIP and of the combined company may also be subject to limitation as a result of ownership changes.

As of December 31, 2022, Diffusion had U.S. federal and state NOL carryforwards of approximately \$34.2 million and EIP had U.S. federal NOL carryforwards and state NOL carryforwards of \$38.2 million and \$37.2 million, respectively. Under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change" (within the meaning of Section 382 of the Code ("Section 382")), the corporation's NOL carryforwards and certain other tax attributes (such as research tax credits) arising before the ownership change are subject to limitation on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points (by value) over a rolling three-year period. Similar rules may apply under state tax laws. The Merger will result in an ownership change for Diffusion and, accordingly, Diffusion's NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after the Merger. Diffusion's NOL carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on Diffusion's, EIP's, and the combined company's NOL carryforwards. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Diffusion's, EIP's, and the combined company's NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, the combined company's existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

The Merger may have adverse tax consequences.

Subject to the limitations and qualifications described in the section titled “*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*” beginning on page 139 of this proxy statement/prospectus/information statement, in the opinion of Mintz, the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code. This opinion is based on facts and representations contained in representation letters provided by EIP, Diffusion and Merger Sub and on customary factual assumptions, and further assumes that the Merger is completed in the manner set forth in the Merger Agreement and the registration statement on Form S-4 of which this proxy statement/prospectus/information statement forms a part. If the Merger were to fail to so qualify, then each holder of EIP Common Stock generally would recognize gain or loss, as applicable, equal to the difference between (1) the sum of the fair market value of the shares of Diffusion Common Stock received by such U.S. holder in the Merger and the amount of cash received for fractional shares by such U.S. holder in the Merger and (2) its adjusted tax basis in the shares of EIP Common Stock surrendered in exchange therefor. The consequences of the Merger to any particular stockholder will depend on that stockholder’s particular situation. We strongly urge you to consult your own tax advisor to determine the particular tax consequences of the Merger to you.

Once the Merger has closed, there can be no further recourse by either party or its stockholders for a breach of representation or warranty.

The representations and warranties of Diffusion, EIP and Merger Sub contained in the Merger Agreement or any certificate or instrument delivered pursuant to the Merger Agreement will terminate at the Effective Time and there would be no recourse for any breach of such representations and warranties discovered or occurring following the closing of the Merger.

Diffusion may choose to waive certain of its rights under the lock-up agreements signed by certain EIP equityholders if required to meet the listing requirements of Nasdaq.

In April 2023, Diffusion received written notice from the staff (the “Staff”) of the Nasdaq listing qualifications department that the Staff has determined that, in connection with the proposed Merger and pursuant to Nasdaq Listing Rule 5110(a), the combined company will be required to satisfy all of Nasdaq’s initial listing criteria prior to consummation of the Merger in order to obtain such approval. Diffusion currently meets, and anticipates that it will meet at the Effective Time, each of the initial listing requirements for the Nasdaq Capital Market under the “Equity Standard” set forth in Nasdaq Rule 5505(b)(1) other than requirements that the company’s listed securities have (i) a bid price of at least \$4.00 and (ii) an aggregate market value of unrestricted publicly held shares of at least \$15.0 million.

On May 5, 2023, based upon the closing price of the Diffusion Common Stock as reported by Nasdaq of \$3.81, the aggregate market value of unrestricted publicly held shares of Diffusion Common Stock was approximately \$7.6 million. Assuming the registration statement of which this proxy statement/prospectus/information statement forms a part is declared effective by the SEC prior to the Effective Time, for purposes of determining Diffusion’s satisfaction of Nasdaq Rule 5505(b)(1), the value of shares issued to former EIP stockholders at the Effective Time of the Merger will generally be added to such amount, except to the extent that such shares are subject to contractual or other restrictions on the transfer thereof.

As further described under “*Agreements Related to the Merger – Lock-Up Agreements*” beginning on page 166, EIP’s directors, executive officers and certain principal stockholders, who beneficially hold 69.3% of EIP Common Stock on an as-converted to common stock basis as of April 1, 2023, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company’s common stock for up to 180 days following the Effective Time. To the extent the aggregate market value of other unrestricted publicly held shares of Diffusion Common Stock is less than \$15 million, Diffusion may choose to waive its rights under any or all of such lock-up agreements in order to increase the amount of unrestricted publicly held shares outstanding. In such an event, the holders of those shares would be permitted to sell or transfer the shares of common stock they will receive in the Merger sooner than they otherwise would, which could result in a decrease to the company’s stock price.

Risks Related to the Reverse Split Proposal

Failure to obtain stockholder approval for the Reverse Split Proposal may result in the combined company being unable to obtain compliance with the minimum bid price requirements for an initial listing on any Nasdaq market tier and may result in Diffusion Common Stock being delisted from the Nasdaq Capital Market. In addition, the Reverse Split may not result in an increase to the combined company's stock price that is sufficient to satisfy Nasdaq's listing requirements so as to qualify for Nasdaq listing and/or Diffusion may fail to satisfy other Nasdaq listing requirements that cannot be cured through a Reverse Split.

As further described elsewhere in this proxy statement/prospectus/information statement under the section titled, “*The Merger Agreement – Conditions to the Closing of the Merger*,” under the terms of the Merger Agreement, one of the conditions to the completion of the Merger is that the existing shares of Diffusion Common Stock shall have been continually listed on Nasdaq as of and from the date of the Merger Agreement through the closing date of the Merger and the shares of Diffusion Common Stock to be issued in the Merger pursuant to the Merger Agreement shall have been approved for listing, subject to official notice of issuance, on Nasdaq after the closing. In April 2023, Diffusion received written notice from the staff (the “Staff”) of the Nasdaq listing qualifications department that the Staff has determined that, in connection with the proposed Merger and pursuant to Nasdaq Listing Rule 5110(a), the combined company will be required to satisfy all of Nasdaq’s initial listing criteria prior to consummation of the Merger in order to obtain such approval. Diffusion currently meets, and anticipates that it will meet at the Effective Time, each of the initial listing requirements for the Nasdaq Capital Market under the “Equity Standard” set forth in Nasdaq Rule 5505(b)(1) other than requirements that the company’s listed securities have (i) a bid price of at least \$4.00 and (ii) an aggregate market value of unrestricted publicly held shares of at least \$15.0 million.

On May 5, 2023, the closing price of the Diffusion Common Stock as reported by Nasdaq was \$3.81, resulting in an aggregate market value of unrestricted publicly held shares of less than \$10.0 million. Diffusion is required pursuant to the terms of the Merger Agreement to submit to its stockholders a proposal to approve an amendment to its certificate of incorporation to authorize the Diffusion board of directors to effect the Reverse Split of all outstanding shares of its common stock. The Reverse Split, if approved by Diffusion stockholders, may be implemented by the Diffusion board of directors in an effort to increase the per-share market price of Diffusion’s common stock above the minimum bid price requirement under the Nasdaq rules so that the listing of the combined company and the shares of Diffusion Common Stock being issued in the Merger on Nasdaq will be approved. Diffusion has filed a listing application for the combined company with Nasdaq.

If the price of Diffusion Common Stock is less than \$4.00 per share, and if the Reverse Split Proposal is not approved by Diffusion’s stockholders and the Merger is completed, the combined company will likely not be able to obtain compliance with the minimum bid price requirement for an initial listing on any Nasdaq market tier. Further, while it is expected that, if the Reverse Split Proposal is approved and the Reverse Split is implemented, the reduction in the number of outstanding shares of common stock that would result from the Reverse Split would proportionally increase the market price of the combined company’s common stock, the Reverse Split may not result in an increase to the combined company’s stock price that is sufficient to satisfy Nasdaq’s initial listing requirements. There can be no assurances that Nasdaq will approve the listing application, and further, Nasdaq’s determination may not be known at the time stockholders are asked to approve the Merger.

In addition, due to the fact that the Reverse Split would result in a decrease to the number of shares of Diffusion Common Stock outstanding, it is not anticipated that the Reverse Split, even if approved and implemented, will have any direct impact on the combined company’s ability to satisfy the aggregate market value of unrestricted securities requirement for an initial listing. Under the rules and regulations of Nasdaq, new shares that would be issued to EIP’s stockholders at the Effective Time are included in the calculation of the combined company’s aggregate market value of unrestricted shares, provided that such shares are not restricted pursuant to securities laws, contractual lock-up agreements or otherwise. As further described under “*Agreements Related to the Merger – Lock-Up Agreements*” beginning on page 166, EIP’s directors, executive officers and certain principal stockholders, who beneficially held 69.3% of EIP Common Stock on an as-converted to common stock basis as of April 1, 2023, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company’s common stock for up to 180 days following the Effective Time. However, pursuant to the terms of the lock-up agreements, Diffusion may agree to waive its rights under the lock-up agreements of certain EIP stockholders in order for the shares to be considered “unrestricted,” included in the combined company’s aggregate market value of unrestricted securities and, to the extent such amount results in an aggregate amount of at least \$15.0 million in the aggregate, support the combined company’s ability to satisfy the associated Nasdaq initial listing requirement.

If the Reverse Split does not result in an increase to the market price of Diffusion Common Stock sufficient to satisfy the minimum bid price Nasdaq listing criteria, or if Diffusion does not otherwise satisfy Nasdaq's initial listing requirements, Nasdaq may not approve the listing of the combined company and the shares of Diffusion Common Stock that would be issued in the Merger, which would entitle EIP to terminate the Merger Agreement due to Diffusion's failure to satisfy the associated closing condition. Even if Diffusion and EIP agreed to waive the requirement that the Nasdaq application be accepted for listing prior to the consummation of the Merger, and their respective boards of directors determined to proceed with the closing of the Merger in its absence, Nasdaq may notify the combined company of its determination to delist the company's securities based upon the failure to satisfy the initial inclusion criteria. The combined company may appeal the determination to a hearings panel, which will stay the delisting action pending a panel decision. If the combined company does not appeal the determination, its common stock will be delisted. Any potential suspension of the shares of common stock from Nasdaq would likely result in decreased liquidity and increased volatility for the combined company's common stock and would adversely affect the combined company's ability to raise additional capital or to enter into strategic transactions. Any potential suspension of the shares of common stock from Nasdaq would also make it more difficult for stockholders to sell the combined company's common stock in the public market. Furthermore, if Diffusion waives its rights under the lock-up agreements of certain EIP stockholders, these holders would no longer be restricted from transacting in Diffusion Common Stock during the prescribed lock-up period. Any sales by these holders, which could be significant, could put additional downward pressure on the trading price of the Diffusion Common Stock.

For more information regarding the conditions to closing the Merger, see, "*The Merger Agreement – Conditions to the Closing of the Merger*" beginning on page 150, and for more information regarding the ability of the parties to waive conditions to the Merger, see "*Risks Related to the Merger — Diffusion or EIP may waive one or more conditions to the Merger without re-soliciting stockholder approval*" beginning on page 40.

Diffusion's board of directors will determine the Reverse Split ratio in its discretion (subject to mutual agreement with EIP regarding the Reverse Split ratio assuming the Merger Agreement remains in effect at such time) and may consider a variety of factors in making its determination.

If the Reverse Split Proposal is approved by Diffusion's stockholders, Diffusion intends to effect the Reverse Split, with the exact ratio to be determined in the discretion of Diffusion's board of directors in accordance with the terms set forth in the Reverse Split Proposal (subject to mutual agreement with EIP regarding the Reverse Split ratio assuming the Merger Agreement remains in effect at such time). If the Merger is not approved or consummated, Diffusion's board of directors may elect to proceed with the Reverse Split even in the absence of completion of the Merger, and the exact ratio of the Reverse Split will be determined by Diffusion's board of directors.

The proposed Reverse Split may not increase the combined company's stock price over the long-term.

There is no assurance however that the per-share market price of Diffusion Common Stock will remain at such increased level for any meaningful period of time. While the reduction in the number of outstanding shares of Diffusion Common Stock should proportionally increase the market price of Diffusion Common Stock, it cannot be assured that the proposed Reverse Split will increase the market price of Diffusion Common Stock by a multiple of the proposed Reverse Split ratio, or result in any permanent or sustained increase in the market price of Diffusion Common Stock, which is dependent upon many factors, including the combined company's business and financial performance, general market conditions, and prospects for future success. Therefore, while the stock price of the combined company might meet the initial listing requirements for the Nasdaq Capital Market initially, it cannot be assured that it will continue to do so.

The proposed Reverse Split may lead to a decrease in the combined company's overall market capitalization.

The Reverse Split may be viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the proposed Reverse Split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of Diffusion Common Stock will remain the same after the proposed Reverse Split is effected, or that the proposed Reverse Split will not have an adverse effect on the stock price of Diffusion Common Stock due to the reduced number of shares outstanding after the proposed Reverse Split. In addition, any such decrease in the combined company's overall market capitalization would exacerbate any deficiency in satisfying the aggregate market value of unrestricted securities requirement, which may require Diffusion to waive its rights under lock-up agreements with additional EIP stockholders.

The proposed Reverse Split may decrease the liquidity of the combined company's common stock.

The liquidity of the combined company's common stock could be adversely affected by the reduced number of shares outstanding after the proposed Reverse Split is effected. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company's common stock.

Risks Related to Diffusion

Risks Related to Diffusion's Business, Financial Position, Results of Operation, and Organizational Structure if the Merger is Not Completed

If the Merger is not completed, the Diffusion board of directors may decide to pursue a liquidation and dissolution of Diffusion. In such an event, there can be no assurances as to the amount or timing of available cash left, if any, to distribute to Diffusion stockholders after paying its debts and other obligations and setting aside funds for reserves.

While Diffusion has entered into the Merger Agreement with EIP, the closing of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits Diffusion expects or enhance stockholder value. If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, Diffusion may be required to pay EIP a termination fee of \$765,000. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, Diffusion will have incurred significant fees and expenses, most of which must be paid whether or not the Merger is completed.

If, for any reason, the Merger does not close, the Diffusion board of directors may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the various assets of Diffusion including TSC, resume its research and development activities and continue to operate the business of Diffusion. Any of these alternatives would be costly and time-consuming and would likely require that Diffusion obtain additional funding. Diffusion can make no assurances that it would be able to obtain additional financing or find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement or that any such alternatives are possible or would be successful, if pursued. To the extent that Diffusion seeks and is able to raise additional capital through the sale of equity or convertible debt securities, Diffusion stockholders' ownership interest would be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of Diffusion's common stockholders. Investors may demand significant discounts to market prices or that Diffusion agrees to restrictive covenants or other limitations on Diffusion's ability to operate Diffusion's business, and conditions in the capital markets may make equity and debt financing more difficult to obtain or negatively impact Diffusion's ability to complete a financing transaction at all. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting Diffusion's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Diffusion raises funds through strategic transactions or marketing, distribution, or licensing arrangements with third parties, Diffusion may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to it. If Diffusion is unable to raise additional capital in sufficient amounts or on terms acceptable to us, Diffusion may have to significantly delay, scale back, discontinue the development or commercialization of one or more of Diffusion's product candidates, or seek alternative financing opportunities such as collaborations or licensing opportunities. Even if Diffusion is able to pursue such alternatives, the failure to complete the Merger may result in negative publicity and/or a negative impression of Diffusion in the investment community, could significantly harm the market price of Diffusion Common Stock and may affect Diffusion's relationship with employees and other partners in the industry.

If the Merger is not completed, the Diffusion board of directors may decide that it is in the best interests of the Diffusion stockholders to dissolve the company and liquidate its assets. In that event, the amount of cash available for distribution to the Diffusion stockholders would depend heavily on the timing of such decision and, ultimately, such liquidation since the amount of cash available for distribution continues to decrease as Diffusion funds its operations and incurs fees and expenses related to the Merger. In addition, if the Diffusion board of directors were to approve and recommend, and the Diffusion stockholders were to approve, a dissolution of Diffusion, it would be required under the DGCL to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to the Diffusion stockholders. As a result of this requirement, a portion of Diffusion's assets may need to be reserved pending the resolution of such obligations. In addition, Diffusion may be subject to litigation or other claims related to a liquidation and dissolution of the company. If a liquidation and dissolution were pursued, the Diffusion board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, the Diffusion stockholders could lose all or a significant portion of their investment in the event of a liquidation and dissolution of Diffusion.

Diffusion is substantially dependent on Diffusion's remaining employees to facilitate the consummation of a strategic transaction, including the Merger.

On February 16, 2023, Diffusion announced its commitment to a reduction in force impacting six of Diffusion's 13 employees, including the departure of Dr. Christopher D. Galloway, M.D., Diffusion's former Chief Medical Officer, and Ms. Raven Jaeger, Diffusion's former Chief Regulatory Officer, in each case, effective March 1, 2023. Diffusion's ability to successfully complete a strategic transaction depends in large part on Diffusion's ability to retain certain of Diffusion's remaining personnel. Despite Diffusion's efforts to retain these employees, one or more may terminate their employment with Diffusion on short notice. The loss of the services of any of these employees could potentially harm Diffusion's ability to consummate a strategic transaction, to run Diffusion's day-to-day operations, or fulfill Diffusion's reporting obligations as a public company.

Diffusion currently generates no revenue from the sale of products, have incurred significant losses since Diffusion's inception, have a history of net losses and negative cash flow from operations, expect to incur losses for the foreseeable future, and may never become profitable. In addition, Diffusion's operating results may fluctuate significantly, which makes Diffusion's future operating results difficult to predict and could cause Diffusion's operating results to fall below expectations. As a result, any investment in Diffusion Common Stock is speculative and risky.

Diffusion is a clinical stage biotechnology company and, as a result, it has a limited operating history from which to assess how it will respond to competitive, economic, or other challenges to Diffusion's business, and Diffusion's business and prospects must be considered in light of the risks and uncertainties frequently encountered by similarly situated companies.

Diffusion has limited cash resources, has generated substantial net losses and negative cash flow from operations since Diffusion's inception, and Diffusion continues to incur significant research, development, and other expenses related to Diffusion's ongoing operations. To date, Diffusion has not yet obtained regulatory approvals for any of Diffusion's product candidates and, accordingly, has not generated any revenues from the sale of products. Diffusion expects to continue to incur losses and negative cash flow for the foreseeable future. Furthermore, Diffusion's future operating results may fluctuate due to a variety of other factors, many of which are outside of Diffusion's control and may be difficult to predict, including the delays in Diffusion's product development programs including as a result of regulatory review, increased expenditures related to manufacturing or the enforcement of intellectual property rights, other litigation costs, changes in accounting policies, or other unanticipated events.

Diffusion's ability to generate sufficient revenues from any of Diffusion's product candidates, if approved, will depend on numerous factors described throughout this proxy statement/prospectus/information statement. Even if Diffusion is able to successfully develop and receive regulatory approval for any of Diffusion's product candidates, it does not know if or when any such product will achieve commercial success or generate revenue for Diffusion, and Diffusion will incur significant costs associated with the commercialization that will need to be offset by revenue before achieving a profit. Diffusion may also in the future enter into collaboration agreements and license agreements with other companies that include milestone expenditures and payments, in which case Diffusion's ability to generate revenue or achieve profitability may be dependent on the achievement of those milestones. Even if Diffusion achieves profitability in the future, Diffusion may not be able to sustain profitability in subsequent periods, and Diffusion's prior losses and expected future losses have had and will continue to have an adverse effect on Diffusion's stockholders' equity. Furthermore, due to the uncertainty of the drug development process, Diffusion is often unable to predict the timing or amount of increased expenses, or when Diffusion will be able to achieve or maintain profitability, if at all.

Diffusion's forecast of the period of time through which Diffusion's financial resources will be adequate to support Diffusion's operations is a forward-looking statement and involves the associated risks and uncertainties. Although Diffusion has based this estimate on assumptions that Diffusion believes to be reasonable, they may prove to be wrong, Diffusion could utilize Diffusion's available capital resources sooner than it currently expects, and actual results could vary greatly from Diffusion's expectations expressed in this proxy statement/prospectus/information statement as a result.

Diffusion's forecast of the period of time through which Diffusion's financial resources will be adequate to support Diffusion's operations is a forward-looking statement and involves the associated risks and uncertainties. Although Diffusion has based this estimate on assumptions that Diffusion believes to be reasonable, they may prove to be wrong, Diffusion could utilize Diffusion's available capital resources sooner than it currently expects, and actual results could vary greatly from Diffusion's expectations expressed in this proxy statement/prospectus/information statement as a result. The magnitude and timing of Diffusion's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- whether and when the closing of the Merger occurs;
- the number, development stage, and other characteristics of product candidates that Diffusion chooses to develop, including any product candidates that Diffusion may in-license or otherwise acquire in the future through Diffusion's strategic review process or otherwise;
- the clinical development plans Diffusion establishes for these product candidates;
- the magnitude of costs associated with filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the initiation, progress, timing, costs, and results of clinical trials for such product candidates;
- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that Diffusion performs more studies than those that Diffusion currently expects;
- the cost and timing of completion of becoming a commercial organization; and
- the effect of competing technological and market developments.

Whether or not the Merger is completed, Diffusion may not be able to enter into a transaction with a suitable acquiror or licensee for TSC or any transaction entered into may not be on terms that are favorable to Diffusion.

As previously announced, in connection with its strategic review process, Diffusion made the strategic decision to voluntarily pause significant portions of the TSC development program. Currently, Diffusion believes the primary path available to derive value from its TSC-related assets would be to find a suitable acquiror or licensee for the asset. Although Diffusion management has contacted numerous parties to assess their potential interest in such a transaction, to date, Diffusion has been unable to identify an interested counterparty. Furthermore, even if Diffusion is able to identify such a counterparty, supporting diligence activities conducted by potential acquirors or licensees and negotiating the financial and other terms of an agreement or license are typically long and complex processes, and the results of such processes cannot be predicted.

There can be no assurance that Diffusion will enter into any transaction as a result of this effort or that any transaction involving Diffusion's TSC-related assets will be entered into or, if entered into, will be on terms that are favorable to Diffusion. Furthermore, Diffusion cannot predict the impact that such a transaction or, alternatively, a failure to monetize the TSC assets in any material way, might have on its stock price.

In connection with Diffusion's strategic decision to voluntarily pause significant portions of the TSC development program, Diffusion may become involved in disagreements or disputes with counterparties relating to the development TSC, which may be time consuming, costly and could divert its efforts and attention from consummating the Merger and harm Diffusion's efforts to seek a partner to continue development of TSC.

Diffusion has entered into various agreements with other counterparties related to the development of TSC which impose a variety of obligations on Diffusion and the counterparties to such agreements. As a result of Diffusion's decision to pause significant portions of the TSC development program and subsequent decision to enter into the Merger Agreement, Diffusion has begun the process of winding down the majority of its own operations relating to TSC while seeking a partner for the further development of TSC. While Diffusion is not aware of any such matters as of the date of this proxy statement/prospectus, disagreements and disputes between Diffusion and certain counterparties related to this wind-down may arise in the future regarding each parties' obligations under these agreements. Any such disagreement or dispute could become time consuming, costly and could divert Diffusion's efforts and attention from consummating the Merger and could harm its efforts to seek a partner to continue development of TSC. Any disagreements or disputes with such parties that lead to litigation, arbitration or similar proceedings will result in Diffusion incurring significant legal expenses, as well as potential significant legal liability.

Regulatory authorities, including the FDA, may not accept data from clinical trials conducted outside of their jurisdiction.

Diffusion's clinical trial conducted during 2020-21 evaluating TSC in patients with COVID-19 was conducted in Bucharest, Romania and, if the Merger is completed, the combined company may in the future conduct additional clinical trials evaluating its product candidates outside the U.S. The acceptance of trial data from clinical trials conducted outside the U.S. by the FDA may be subject to certain conditions or may not be accepted at all, and other comparable non-U.S. regulatory authorities may have similar restrictions and conditions with respect to clinical trials conducted outside of their jurisdiction. In cases where data from non-U.S. clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of non-U.S. data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many comparable non-U.S. regulatory authorities have similar approval requirements.

There can be no assurance that the FDA will accept data from trials conducted outside of the United States or that any comparable non-U.S. regulatory authority will accept data from trials conducted outside of the applicable jurisdiction. If the FDA or any comparable non-U.S. regulatory authority does not accept such data or believes that additional data is necessary to supplement such data, it would result in the need for additional trials, which would be costly and time-consuming, could delay a product candidate's development plan, and which may result in product candidates not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the U.S. may also expose us to additional risks, including risks associated with the following: additional foreign regulatory requirements; foreign exchange fluctuations; compliance with foreign manufacturing, customs, shipment and storage requirements; the failure of enrolled subjects in foreign countries to adhere to clinical protocol as a result of differences in SOC; cultural differences in medical practice and clinical research; diminished protection of intellectual property rights; and compliance with general local legal requirements.

General Risks Related to Diffusion's Business, Financial Condition, Results of Operations, and Organizational Structure if the Merger is not Completed.

Diffusion's business, financial condition, or results of operations may also be materially adversely affected by a number of general risks related thereto and to Diffusion's organizational structure that are not specific to Diffusion, including:

- If Diffusion fails to maintain an effective system of internal control over financial reporting, Diffusion may not be able to accurately report its financial results or prevent fraud. Furthermore, Diffusion's disclosure controls and procedures are subject to inherent limitations, human error, and other systematic breakdowns, and therefore may not prevent or detect all errors or acts of fraud. As a result, stockholders could lose confidence in Diffusion's financial and other public reporting, which could harm Diffusion's business, financial condition, or results of operations.

- As Diffusion, the industry in which we operate, and the world-at-large become increasingly virtual, Diffusion’s acquisition and implementation of additional information technology solutions and Diffusion’s compliance with global privacy and data security requirements could result in additional costs and liabilities or inhibit Diffusion’s ability to collect and process data globally. Furthermore, any failure to comply with applicable requirements or best practices – as well as other events outside of Diffusion’s control – could result in a security breach or other disruption to Diffusion’s information technology systems, limit Diffusion’s capacity to effectively monitor and control Diffusion’s operations, compromise Diffusion’s or third parties’ confidential information, or otherwise adversely affect Diffusion’s business, financial condition, or results of operations.
- Diffusion incurs significant costs as a result of Diffusion’s public company status and devote substantial management time to operating as a public company, including complying with the applicable requirements of the Securities Act, the Exchange Act, the Dodd-Frank Act, SOX, and the rules and regulations of Nasdaq. If, in the future, Diffusion is required to include in Diffusion’s annual report an attestation of Diffusion’s independent registered public accounting firm regarding internal control over financial reporting, the amount of these compliance costs would increase significantly.
- Although Diffusion has in place business continuity and disaster recovery plans, Diffusion’s business, financial condition, or results of operations could be negatively affected by volatility, disruptions, or other uncertainty caused by market fluctuations, economic downturns or unfavorable global economic conditions, pandemics, natural disasters or other catastrophic events, events of war, terrorism, or other man-made problems, or other geopolitical events outside of Diffusion’s control, such as the ongoing war in Ukraine, the COVID-19 pandemic and Brexit.
- If Diffusion fails to comply with applicable laws and regulations, including the healthcare laws and regulations described under the heading, “Diffusion Business – Government Regulation” beginning on page 183 and applicable environmental, health, and safety laws and regulations, Diffusion could become subject to fines, penalties, or other consequences.

Risks Related to Ownership of Diffusion Common Stock if the Merger is Not Completed

Provisions in Diffusion’s corporate charter documents and under Delaware law could make an acquisition of the company, which may be beneficial to Diffusion’s stockholders, more difficult and may prevent attempts by Diffusion’s stockholders to replace or remove its current directors and members of management.

Provisions in Diffusion’s certificate of incorporation, as amended, and its amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the company that stockholders may consider favorable, including transactions in which Diffusion’s stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of Diffusion Common Stock, thereby depressing the market price of its common stock. In addition, because Diffusion’s board of directors is responsible for appointing the members of its management team, these provisions may frustrate or prevent any attempts by Diffusion’s stockholders to replace or remove its current management by making it more difficult for stockholders to replace members of Diffusion’s board of directors. Among other things, these provisions:

- allow the authorized number of Diffusion’s directors to be changed only by resolution of its board of directors;
- limit the manner in which stockholders can remove directors from Diffusion’s board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to Diffusion’s board of directors;
- limit who may call stockholder meetings and Diffusion stockholders’ ability to act by written consent;
- authorize Diffusion’s board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by Diffusion’s board of directors; and

- require the approval of the holders of at least 2/3 of the votes that all Diffusion's stockholders would be entitled to cast to amend or repeal specified provisions of Diffusion's restated certificate of incorporation or for stockholders to amend or repeal Diffusion's amended and restated bylaws.

Moreover, because Diffusion is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which generally prohibits a person who, together with their affiliates and associates, owns 15% or more of a company's outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15% or more of the company's outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Diffusion's certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by its stockholders, which could discourage lawsuits against the company and its directors, officers and employees.

Diffusion's restated certificate of incorporation provides that, unless Diffusion consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for certain proceedings, including: (1) any derivative action or proceeding brought on Diffusion's behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of Diffusion's directors, officers, employees or stockholders to the company or its stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of Diffusion's restated certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

These exclusive-forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit the ability of Diffusion's stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with Diffusion or its directors, officers or employees, which may discourage such lawsuits against Diffusion and its directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in Diffusion's restated certificate of incorporation to be inapplicable or unenforceable in an action, Diffusion may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect its business, financial condition and operating results.

If Diffusion cannot continue to satisfy the Nasdaq Capital Market continued listing standards and other Nasdaq rules, Diffusion Common Stock could be delisted, which would harm Diffusion's business, the trading price of Diffusion Common Stock, Diffusion's ability to raise additional capital and the liquidity of the market for Diffusion Common Stock.

Diffusion Common Stock is currently listed on the Nasdaq Capital Market. To maintain the listing of Diffusion Common Stock on the Nasdaq Capital Market, Diffusion is required to meet certain listing requirements. In the event that Diffusion Common Stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of Diffusion Common Stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult for us to raise capital and for Diffusion's stockholders to dispose of, or obtain accurate price quotations for, Diffusion Common Stock, and there would likely also be a reduction in Diffusion's coverage by securities analysts and the news media, which could cause the price of Diffusion Common Stock to decline further.

Diffusion holds its cash and cash equivalents that it uses to meet its working capital needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

Diffusion holds its cash and cash equivalents that we use to meet its working capital needs in deposit accounts at multiple financial institutions. The balance held in these accounts may exceed the Federal Deposit Insurance Corporation (“FDIC”), standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which Diffusion holds such funds fails or is subject to significant adverse conditions in the financial or credit markets, Diffusion could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact Diffusion’s short-term liquidity and ability to meet its obligations.

For example, on March 10, 2023, Silicon Valley Bank (“SVB”), and on March 12, 2023, Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which Diffusion holds funds for working capital were to fail, Diffusion cannot provide any assurances that such governmental agencies would take action to protect its uninsured deposits in a similar manner.

Diffusion also maintains investment accounts with other financial institutions in which it holds its investments and, if access to the funds Diffusion uses for working capital is impaired, Diffusion may not be able to sell investments or transfer funds from its investment accounts to new accounts on a timely basis sufficient to meet its working capital needs.

Risks Related to Diffusion’s Intellectual Property if the Merger is Not Completed

Diffusion has paused significant portions of its TSC development activities. If Diffusion chooses to pursue further development of TSC or any other product candidate, Diffusion may not be able to obtain or enforce patent rights or other intellectual property rights that cover its product candidates and technologies that are of sufficient breadth to prevent third parties from competing against Diffusion.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing, and marketing of health care products competitive with those that Diffusion is developing, and Diffusion faces competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions. Accordingly, our ability to obtain and maintain patent protection in both the U.S. and non-U.S. jurisdictions will be critical to our Diffusion’s to successfully develop, obtain regulatory approval for, and, in particular, commercialize TSC and its other product candidates. These protections are and will be essential to preserving and protecting Diffusion’s novel inventions, proprietary developments, and trade secrets and to preventing third parties from infringing upon them. In particular, Diffusion’s ability to protect any of its product candidates from unauthorized or infringing use by third parties depends in substantial part on its ability to obtain and maintain valid and enforceable patents in the U.S. and worldwide.

Diffusion’s patent portfolio includes patents and patent applications in the U.S. and other major markets covering its technology with varying scope, including issued U.S. patents related to composition of matter, formulation, methods of delivery, and methods of use and the scope of coverage vary from country to country. Although Diffusion believes that its intellectual property position is strong and is currently assessing its operations and existing portfolio for additional intellectual property opportunities, Diffusion does not have – and may be unable to obtain – patent protection for every aspect of its technology. For aspects of Diffusion’s technology for which it does not have patent coverage, or in countries where Diffusion does not have granted patents, Diffusion may not have any ability to prevent the unauthorized use of its technologies or technologies substantially similar to Diffusion’s, and any patents that Diffusion may obtain in the future may be narrow in scope and thus easily circumvented by competitors. Further, in countries where Diffusion does not have granted patents, third parties may be able to make, use or sell products identical to or substantially similar to, Diffusion’s product candidates.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, Diffusion’s ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. The patent application process, also known as patent prosecution, is expensive and time-consuming, and Diffusion may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that Diffusion will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Despite any past and future efforts to obtain additional intellectual property and patent protections for product candidates, there is no assurance Diffusion will obtain such protections through its applications. Therefore, these and any of Diffusion’s patents and applications may not be prosecuted and enforced in an optimal manner. It is also possible that defects of form in the preparation or filing of Diffusion’s patents or patent applications may exist, or may arise in the future, such as with respect to inadvertent prior public disclosures, proper priority claims, inventorship, claim scope, or patent term adjustments. If Diffusion’s current or future third-party development partners are not fully cooperative or disagree with Diffusion as to the prosecution, maintenance, or enforcement of any patent rights, those patent rights could be compromised and Diffusion might not be able to prevent third parties from making, using and selling competing products. Moreover, Diffusion’s competitors may independently develop equivalent knowledge, methods and know-how. Accordingly, Diffusion cannot guarantee that any patents will issue from any of its currently pending patent applications, which could impair its ability to prevent competition from third parties.

Even for aspects of Diffusion's technology for which it has obtained, or obtains in the future, patent protection, the complexity of legal and factual questions underlying such claims means they may not provide Diffusion with sufficient protection for its product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. Diffusion cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide Diffusion with any significant protection against competitive products or otherwise be commercially valuable to Diffusion. Third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents it owns or licenses, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents it holds or pursues with respect to its product candidates is challenged, it could dissuade companies from collaborating with Diffusion to develop, or threaten our ability to commercialize, its product candidates. Changes in either the patent laws or in the interpretations of patent laws in the U.S. and other countries may diminish the value of Diffusion's intellectual property.

In addition, patents have a limited lifespan, presenting further challenges in effectively protecting Diffusion's technologies and associated commercial position. In the U.S., the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available under a variety of legislative and regulatory avenues but often the life afforded by these extensions and the protections they afford are limited relative to full patent protection. The extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which Diffusion can market a product candidate under patent protection, which may particularly affect the profitability of Diffusion's early-stage product candidates. Even if patents covering Diffusion's products are obtained, once the patent life has expired, Diffusion may be open to competition from competitive products. If one of Diffusion's products requires extended development, testing and/or regulatory review, patents protecting such products might expire before or shortly after such products are commercialized. As a result, Diffusion's owned and licensed patent portfolio may not provide Diffusion with sufficient rights to exclude others from commercializing products similar or identical to Diffusion's, which could have a material adverse effect on Diffusion's business, financial condition and results of operations.

For example, historically, Diffusion's primary focus since the founding of Diffusion LLC in the early 2000s has been developing TSC and, as a result, portions of Diffusion's patent portfolio, including certain patents related to TSC's composition of matter, have expired or will expire in the near future. While the Company actively engages in efforts to obtain additional patent protection covering Diffusion's product candidates, there is no assurance that Diffusion will successfully obtain such patent protection. Furthermore, if Diffusion is unable to obtain regulatory approval of and successfully commercialize Diffusion's product candidates prior to the expirations of key underlying patents, Diffusion's owned and licensed patent portfolio may not provide Diffusion with sufficient rights to exclude others from commercializing products similar or identical to Diffusion's.

Furthermore, the laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for Diffusion to stop the infringement of Diffusion's patents or marketing of competing products in violation of Diffusion's proprietary rights generally in those countries. If Diffusion encounters such difficulties in protecting or are otherwise precluded from effectively protecting Diffusion's intellectual property in foreign jurisdictions, Diffusion's business prospects could be substantially harmed.

Proprietary trade secrets and unpatented know-how are also very important to Diffusion's business. Although we have taken steps to protect Diffusion's trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or Diffusion may be unable to protect Diffusion's rights. Diffusion also has limited control over the protection of trade secrets used by Diffusion's suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that Diffusion would have adequate remedies for any breach or that Diffusion's trade secrets and unpatented know-how will not otherwise become known or be independently discovered by Diffusion's competitors. If trade secrets are independently discovered, Diffusion would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using Diffusion's trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secret information.

If we are unable to adequately obtain or enforce Diffusion's patent and other intellectual property rights for any reason, it could materially and adversely affect Diffusion's business, financial condition, and results of operations. For more information about Diffusion's intellectual property and Diffusion's competition, see the information included under the heading, "Diffusion Business – Product Development" beginning on page 181.

If Diffusion becomes involved in lawsuits to protect or enforce Diffusion's patents or other intellectual property, or if Diffusion is sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on Diffusion's business, financial condition, or results of operations.

Diffusion's ultimate commercial success depends upon Diffusion's ability to develop, manufacture, market, and sell Diffusion's product candidates and use Diffusion's proprietary technologies in the U.S. and non-U.S. markets. In order to do so, it is critical that we prevent third parties from infringing on Diffusion's intellectual property rights and that we operate Diffusion's business without infringing on the intellectual property rights of others.

However, numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in fields relating to Diffusion's product candidates, their potential methods of delivery, potential indications they may be used to treat, and their other features, and, as more patents are issued over time, the risk increases that others may assert that Diffusion's product candidates, technologies, or methods of delivery or use infringe their patent or other intellectual property rights, or that we discover a third party infringing on Diffusion's rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems, or their methods of use, which of these patents may be valid and enforceable, and what inventions or technologies may be claimed by non-public patent applications. Patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their first non-provisional filing and publications in the scientific literature often lag behind actual discoveries, meaning Diffusion cannot be certain whether others, including Diffusion's competitors, have filed patent applications for technology covered by patents or Diffusion's pending applications and whether any such filing has priority over Diffusion's own applications or patents.

In the biopharmaceutical and pharmaceutical industries in particular, there is a substantial amount of litigation involving patent and other intellectual property rights. This type of litigation may occur unexpectedly but may also be prompted by specific events, such as a patent application being made public by the U.S. Patent and Trademark Office ("USPTO") or a non-U.S. governmental authority or under Paragraph IV of the Hatch-Waxman Amendments.

As of the date of this proxy statement/prospectus/information statement, no litigation asserting infringement claims has been brought against Diffusion, nor has Diffusion filed such a claim against any third party. However, Diffusion cannot assure you that the development or future commercialization of any of Diffusion's product candidates or other technologies will not result in claims that Diffusion's activities infringe on the existing or future intellectual property rights of third parties. Furthermore, potential competitors may infringe Diffusion's intellectual property, including Diffusion's patents.

Diffusion may be required to file infringement claims to stop third-party infringement or unauthorized use or, if a third party claims Diffusion is infringing on their rights, respond to such claims. This process can be expensive and time consuming and could result in a court deciding that a patent of Diffusion's is not valid or is unenforceable, that a third party is not required to stop using a technology Diffusion believes infringes on Diffusion's rights, significant costs, or the diversion of management's time. An adverse determination in any litigation or other proceedings could put one or more of Diffusion's patents at risk of being invalidated, interpreted narrowly, or amended such that they do not cover Diffusion's product candidates in a manner sufficient to support Diffusion's development and commercialization needs or that such product candidate needs to be significantly redesigned, or put Diffusion's pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope. Further, some of Diffusion's competitors may be able to sustain the costs of complex patent litigation more effectively than Diffusion can because they have substantially greater resources.

In addition, interference, derivation, or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to Diffusion's patents or patent applications. Litigation or USPTO proceedings brought by us may fail or may be invoked against Diffusion by third parties. Even if Diffusion is successful in these proceedings, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and the diversion of management's time. Diffusion may not be able to prevent all misappropriation of Diffusion's proprietary rights, particularly in countries with a legal framework that offers limited intellectual property protections or where the costs of enforcement outweigh the commercial and other benefits of maintaining intellectual property protections.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of Diffusion's confidential information could be compromised by disclosure during this type of litigation or other proceedings, including as a result of public announcements of the results of hearings, motions or other interim proceedings or developments, or public access to related documents. This type of disclosure could put Diffusion at a significant competitive disadvantage by disclosing important trade secrets or other proprietary information to Diffusion's competitors and other third parties.

Any litigation or other challenge related to Diffusion's intellectual property could materially and adversely affect Diffusion's business, financial condition, and results of operations.

General Risks Related to Diffusion's Intellectual Property if the Merger is Not Completed

Diffusion's business, financial condition, or results of operations may also be materially adversely affected by a number of general risks related to Diffusion's intellectual property that are not specific to Diffusion, including:

- As is common in the biopharmaceutical and pharmaceutical industries, some of Diffusion's employees were formerly employed by companies in the industry, including Diffusion's competitors or potential competitors, and some of Diffusion's consultants actively work for other companies in the industry. As a result, although Diffusion has in place policies which prohibit the use of third-party confidential information in violation of any obligation to a former employer or otherwise, we may be subject to claims that Diffusion's employees, consultants or independent contractors have wrongfully used or disclosed to Diffusion alleged trade secrets of their former employers or their former or current customers. In addition, if any of Diffusion's current employees or consultants are engaged by a competitor in the future, it is possible that they may appropriate or otherwise improperly use Diffusion's proprietary and confidential information. Any of the foregoing events could result in significant costs and the diversion of time and resources.
- Obtaining and maintaining Diffusion's patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and Diffusion's patent protection could be reduced or eliminated as a result of any non-compliance with these requirements. Diffusion may also abandon certain intellectual property protections that Diffusion would otherwise maintain if Diffusion determines such protections are not expected to provide sufficient value relative to the cost of ongoing maintenance.

- Patent laws and other intellectual property protections available in the U.S., E.U., or other jurisdictions are subject to change. These changes may be unpredictable, weaken Diffusion's overall intellectual property position, increase Diffusion's costs related to maintenance and enforcement, or otherwise diminish the value of patents in general, thereby impairing Diffusion's ability to protect Diffusion's product candidates and maximize Diffusion's return on investment thereon.

Risks Related to the Development, Regulatory Approval, and Commercialization of Diffusion's Product Candidates if the Merger is Not Completed

Notwithstanding the fact that Diffusion has paused significant portions of its TSC development activities, the success of Diffusion if the Merger is not completed would be dependent on the successful development, regulatory approval, and, ultimately, commercialization of its product candidates. However, the drug development process is expensive, time-consuming and uncertain. Diffusion efforts to develop, obtain regulatory approval for, and commercialize any of Diffusion's product candidates could fail at any stage of the development process for a variety of reasons. Furthermore, because the results of preclinical studies and early-stage clinical trials are not necessarily predictive of future results, even if Diffusion is able to advance a product candidate into additional clinical trials, we may not continue to experience favorable results.

If the Merger is not completed, the success of Diffusion, including Diffusion's ability to finance Diffusion's operations and generate revenue in the future, will depend primarily on the successful development, regulatory approval, and, ultimately, commercialization of Diffusion's product candidates. Historically, the majority of Diffusion's product development resources have been dedicated to Diffusion's most advanced product candidate, TSC, and for the foreseeable future, Diffusion's planned expenditures are primarily related to Diffusion's ongoing strategic review process and other costs associated with the conduct of certain preclinical studies and general research and development activities related to TSC. In the future, Diffusion may also seek to develop or commercialize additional product candidates, including product candidates that we may in-license or acquire to supplement Diffusion's internally developed portfolio through Diffusion's ongoing strategic process or otherwise.

The drug development process is very expensive, time-consuming, difficult to design and implement, and its outcome is inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and success in early-stage clinical trials does not ensure that later clinical trials will demonstrate the efficacy and safety of an investigational drug in a manner adequate to support regulatory approval. Countless other companies, including many with greater resources and experience, have failed or suffered significant setbacks attempting to navigate the drug development process, and there can be no assurance that Diffusion will have success where others have failed.

Diffusion's current product candidates remain in early stages of the development process and, if further developed, Diffusion expects that the additional clinical trials necessary to support a new drug application (an "NDA") will take several years to complete. Diffusion does not know whether the clinical trials Diffusion may conduct will demonstrate adequate efficacy and safety or otherwise provide adequate information to result in regulatory approval to market any of Diffusion's product candidates in any particular jurisdiction. Furthermore, the timeline for Diffusion's clinical trials may be delayed in the future for a variety of reasons, including delays related to regulatory and institutional review board ("IRB") review and approval, slower than anticipated rates of enrollment in or early withdrawals from the trial, third party performance issues beyond Diffusion's control including any contract research organization ("CRO") engaged in the conduct of the trial, discovery of series or unexpected toxicities or side effects, or a lack of effectiveness.

Whether Diffusion is able to successfully develop any of Diffusion's product candidates will depend on a large number of factors, including the following:

- Diffusion's ability to complete Diffusion's planned and future clinical trials in a timely manner and Diffusion's ability to fund such trials;
- Diffusion's ability to demonstrate safety and efficacy to the satisfaction of the FDA and similar foreign regulatory authorities, and whether we are required by any such body to conduct additional clinical trials to support approval;

- the receipt of necessary regulatory approvals, including acceptance of Diffusion’s proposed indications and primary endpoint assessments, marketing approvals, and labeling claims;
- a continued acceptable safety profile during development and following approval, including the prevalence, duration and severity of potential side effects experienced; and
- Diffusion’s ability to commercialize successfully, including scaling Diffusion’s manufacturing capabilities, the development of sales and marketing capabilities internally or through a third party, acceptance by physicians and patients of the benefits, safety and efficacy of Diffusion’s treatments.

Any of these factors, many of which are beyond Diffusion’s control, could result in significant delays or an inability to develop, obtain regulatory approvals for, or commercialize Diffusion’s product candidates, and Diffusion may ultimately be able to receive regulatory approval or generate revenue from the sale of any product candidate.

A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in later-stage Phase 3 clinical development even after promising results in earlier preclinical studies or clinical trials. If later-stage clinical trials do not produce favorable results for Diffusion’s product candidates, or Diffusion is unable to complete the necessary clinical trials for any reason (including a lack of funding), Diffusion’s ability to achieve regulatory approval or successfully commercialize may be compromised. At any time, Diffusion may decide or be forced by circumstance to delay or discontinue the development or commercialization of TSC or any of Diffusion’s other product candidates, including as a result of unfavorable results in later-stage clinical trials, changes in Diffusion’s internal product, technology or indication focus, the appearance of new technologies that make Diffusion’s product candidate obsolete, competition from a competing product, or changes in (or failure to comply with) applicable regulatory requirements. If Diffusion decides or are forced to terminate any development program in which Diffusion has invested significant resources, Diffusion may not receive any return on Diffusion’s investment despite the allocation of significant resources, Diffusion may not be able to execute on Diffusion’s business plan effectively, and Diffusion’s business, financial condition, results of operations may be materially and adversely affected.

If the Merger is not completed, even if Diffusion is able to successfully complete the clinical trials and over development activities necessary to submit an NDA to the FDA or an application for marketing approval to an equivalent non-U.S. regulatory authority, Diffusion may be unable to obtain regulatory approval for any product candidates it may attempt to develop, for the indications for which Diffusion initially seek approval or at all. The FDA and similar non-U.S. regulatory authorities have significant discretion in the approval process, including the ability to delay, limit, or deny approval of product candidates. The delay, limitation, or denial of regulatory approval for any of Diffusion’s product candidates would limit or restrict altogether its ability to commercialize the product and generate revenue, which could materially and adversely impact Diffusion’s business, financial condition, and results of operations.

Diffusion currently has no products approved for sale, and Diffusion may never obtain regulatory approval to commercialize any product candidates Diffusion may attempt to develop. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export, and reporting of safety and other post-market information related to drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and abroad, which often differ from country to country. Diffusion will not be permitted to market any of Diffusion’s product candidates in the U.S. until Diffusion receives approval of an NDA or other applicable regulatory filing from the FDA, and Diffusion will not be permitted to market in any non-U.S. countries until Diffusion receives the requisite approval from the applicable regulatory authorities.

To gain approval to market a new drug, the FDA and similar non-U.S. regulatory authorities require the submission of an NDA (or similar application) that contains preclinical and clinical data adequately demonstrating the safety, purity, potency, efficacy, and compliant manufacturing of the product for the intended indication. The FDA and their non-U.S. counterparts have substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of applications for many reasons, including:

- deemed issues with the design or execution of one or more clinical trials;
- deemed deficiencies in the formulation, quality control, labeling, or specifications of the product candidate;

- deemed issues in Diffusion’s manufacturing processes or in the controls or facilities of third-party manufacturers or testing labs with which Diffusion contracts;
- a determination that the data from preclinical studies and clinical trials included in the application is not sufficient to support approval, or do not meet a required level of statistical or clinical significance, including as a result of a differing interpretation of the data than that presented by the Company in Diffusion’s application;
- a determination that the perceived risks of approving the product candidate outweigh the clinical and other benefits of approval;
- a determination that additional preclinical studies or clinical trials are required, either prior to or as a contingency to approval, and, for certain target indications such as pediatric populations, in the targeted sub-population;
- a determination that a product candidate may only be approved on a contingent basis or for a more limited indication or patient population than Diffusion requests;
- a determination that labeling Diffusion believes is necessary or desirable for successful commercialization cannot be approved; or
- unanticipated future changes to the approval process and related regulations.

Historically, of the large number of drugs in development at any given time, only a small percentage successfully complete the regulatory approval processes and are ultimately commercialized. Diffusion’s product candidates may not be approved for sale and marketing by the FDA or any other governmental authority, even if they meet specified endpoints in Diffusion’s clinical trials. The FDA or applicable foreign regulatory agencies may ask us to conduct additional costly and time-consuming clinical trials in order to obtain marketing approval or approval to enter into a further phase of clinical development or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials.

Any delay in obtaining, or inability to obtain, the regulatory approvals necessary to market and sell Diffusion’s product candidates would delay or prevent commercialization and would materially and adversely affect Diffusion’s business, financial condition, and result of operations. Furthermore, if Diffusion determines in the future that the development, approval, or commercial prospects of any product candidate are insufficient to justify Diffusion’s continued expenditure of the associated development and other costs, Diffusion may choose to delay, suspend, or abandon Diffusion’s development or commercialization efforts with respect thereto, which would reduce or eliminate Diffusion’s potential return on investment for those product candidates.

If the Merger is not completed, Diffusion’s ability to develop Diffusion’s product candidates will depend, and, if any of Diffusion’s product candidates are approved, Diffusion’s ability to successfully commercialize Diffusion’s products will depend, in part on Diffusion’s ability to successfully obtain sufficient quantities of the necessary active pharmaceutical ingredients (“APIs”), other component substances and materials, and finished drug product for Diffusion’s product candidates. Diffusion is currently entirely dependent on third parties for the manufacture and supply of Diffusion’s product candidates and their component parts, including, with respect to Diffusion’s product candidate TSC, a sole supplier. Diffusion may be unable to continue to develop or commercialize Diffusion’s product candidates or face significant delays in that process if Diffusion is unable to successfully obtain these materials or manufacture drug product in sufficient quantities.

Maintaining an adequate supply of Diffusion’s product candidates to meet Diffusion’s needs is critical to the success of Diffusion’s business. However, manufacturing and supply of APIs, other substances and materials and finished drug products is a complex and technically challenging process, and changes beyond Diffusion’s direct control can impact the quality, volume, price, and successful delivery of Diffusion’s product candidates or impede, delay, limit or prevent the successful development and commercialization of Diffusion’s product candidates. Mistakes and mishandling are not uncommon in the biopharmaceutical and pharmaceutical industry and can affect successful production and supply significantly.

As of the date of this Annual Report, Diffusion has no internal manufacturing capabilities and therefore Diffusion does not have direct control over Diffusion's ability to maintain drug supply sufficient to serve Diffusion's needs for Diffusion's ongoing and planned clinical trials or, if any of Diffusion's product candidates are approved, commercialization. Although Diffusion is ultimately responsible for ensuring compliance with regulatory requirements such as current good manufacturing practices ("cGMPs"), Diffusion is dependent on Diffusion's third-party contract manufacturing operations ("CMOs") and other contract suppliers and manufacturers for the manufacture of Diffusion's drug product, including both APIs and finished products, as well as day-to-day compliance with cGMPs and certain other manufacturing-related regulatory requirements. Facilities used by Diffusion's contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection, provide regulators with certain technical information, and be approved by the FDA and other relevant regulatory authorities to confirm compliance with cGMP requirements and other regulatory requirements. If the safety of TSC or any of Diffusion's other product candidates (or any component thereof) is found in the future to be compromised, Diffusion may not be able to successfully commercialize or obtain regulatory approval for the product candidate, and we may be held liable for injuries sustained as a result.

Any disruption in Diffusion's relationship with these third parties or their ability to manufacture the APIs and finished drug product we need for Diffusion's clinical trials and other development activities could result in significant delays in Diffusion's anticipated development timelines and/or significant additional supply costs. Such a disruption could be the result of any number of reasons, including contractual disputes with Diffusion's partners, regulatory issues with Diffusion's partners or at their facilities (whether or not related to Diffusion or Diffusion's drug product), financial issues faced by Diffusion's partners (including bankruptcy or insolvency), damages to Diffusion's partners' facilities or equipment, communication breakdowns, or acts of God. For example, during 2021 Diffusion faced certain delays in the manufacturing process for planned, new batches of TSC drug product due to the fact that, in connection with the U.S. federal government's Operation Warp Speed initiative in response to the COVID-19 pandemic, the facility at which Diffusion's former, primary CMO partner conducts significant portions of the TSC manufacturing process had been mandated to devote the majority of the facility's available resources to the manufacture of components of the COVID-19 vaccine.

Amplifying this risk is the fact that, notwithstanding the improvements made to Diffusion's supply chain during 2021, Diffusion currently depends upon a sole source to manufacture Diffusion's API for TSC and other aspects of Diffusion's manufacturing process, limiting Diffusion's available options to troubleshoot these issues. Although Diffusion actively manages this third-party relationship to ensure continuity, quality, and compliance with regulations and Diffusion intends to identify and develop alternative manufacturing and supply alternatives in the future, this process remains ongoing, will take time, and will involve significant costs. Even with these efforts, some events beyond Diffusion's control, including global instability due to political unrest or from an outbreak of pandemic or contagious disease, such as COVID-19, could result in supply chain disruptions or the complete or partial failure of these manufacturing services. Any such failure or disruptions could materially adversely affect Diffusion's business, financial condition, cash flows, and results of operations. Furthermore, due to the significant regulatory oversight of the pharmaceutical manufacturing process, any changes in the identity of Diffusion's third-party partners or in Diffusion's manufacturing processes – even if in the best interests of the Company and successful – could result in regulatory and other delays, as well as significant additional costs. In addition, if Diffusion's current supplier terminated Diffusion's arrangement or failed to meet Diffusion's supply needs for any reason prior to the time Diffusion is able to identify sufficient alternative manufacturing capacity, Diffusion may be forced to delay Diffusion's development plans significantly.

Diffusion's CMO and other manufacturing and supply partners are also engaged to supply and manufacture materials or products for other biopharmaceutical and pharmaceutical companies, exposing them to regulatory risks unrelated to the work they are doing for Diffusion but which may nevertheless impact their ability to meet their contractual requirements to us or otherwise impede their ability to supply Diffusion with sufficient quantities of drug product. Failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of Diffusion's product candidates or if it withdraws its approval in the future, even if such lack of approval is unrelated to Diffusion or Diffusion's product candidates, Diffusion may need to find alternative supply or manufacturing facilities.

In addition, to date we have only manufactured TSC and Diffusion's other product candidates in relatively small quantities for preclinical studies and clinical trials. As Diffusion prepares for additional, later-stage clinical trials and potential commercialization, Diffusion will need to take steps to substantially increase the scale at which Diffusion is able to produce TSC, its API, and its other component parts. In order to meet these needs, Diffusion's CMOs and suppliers will need to produce Diffusion's API, other components, and finished product in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any of such drug substance and product candidates in a timely or cost-effective manner or at all. Even if such a scale up is possible, it may require additional processes, technologies, and validation studies, which are costly, may not be successful, and which the FDA and foreign regulatory authorities would need to review and approve prior to any commercial sale of TSC or any other product candidate. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or in combination with other components added during the process of manufacturing, packaging, shipping, or storage.

Diffusion's reliance on contract manufacturers and suppliers further exposes Diffusion to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate Diffusion's trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of Diffusion's suppliers are located outside of the United States. This may give rise to difficulties in importing Diffusion's product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

Any of these factors could cause a delay or termination of preclinical studies, clinical trials, other development activities, regulatory submissions or approvals of Diffusion's product candidates, or, if any of Diffusion's product candidates is approved, commercial supply, and could result in significant, unanticipated costs or an inability to effectively develop Diffusion's products candidates or commercialize Diffusion's approved products on a timely basis, or at all, which could materially and adversely affect Diffusion's business, financial condition, and results of operations.

If the Merger is not completed, Diffusion expects to rely on third-party CROs and other third parties to conduct and oversee Diffusion's clinical trials and other aspects of Diffusion's development process for Diffusion's product candidates. If these third parties do not meet Diffusion's requirements or otherwise conduct the trials or perform the other services for which they are engaged, Diffusion may not be able to successfully develop, obtain regulatory approval for, or commercialize Diffusion's product candidates when expected or at all. Furthermore, if Diffusion is not able to establish and maintain the necessary collaborative relationships with Diffusion's CROs and other third-party partners, Diffusion may have to alter Diffusion's development and commercialization plans.

Conducting Diffusion's clinical trials in a safe, compliant, and timely manner is critical to Diffusion's success. Diffusion has historically relied on third-party CROs to conduct and oversee Diffusion's clinical trials and other aspects of Diffusion's product development, as well as various medical institutions, clinical investigators, contract laboratories, consultants, and other third parties to design and conduct Diffusion's trials, to analyze the results therefrom, and to ensure that the trials are conducted in accordance with Diffusion's clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practices ("GCP"). These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data therefrom, as Diffusion controls only certain aspects of their activities and relies heavily on them to execute Diffusion's trials in a safe, compliant, and timely manner. Although Diffusion may internalize portions of these functions if and as Diffusion's organization grows, Diffusion expects to continue to rely on these third parties to a significant degree in the future.

If any of Diffusion's CROs, clinical trial sites, or other third-party partners terminate their involvement in one of Diffusion's clinical trials (or with Diffusion entirely) for any reason, Diffusion may not be able to enter into alternative arrangements sufficient to meet Diffusion's needs, on a timely basis, on commercially reasonable terms, or at all. In addition, if Diffusion's relationship with clinical trial sites is terminated, Diffusion may incur significant additional costs or experience the loss of follow-up information on patients enrolled in Diffusion's ongoing clinical trials, unless Diffusion is able to transfer the care of those patients to another qualified clinical trial site.

Diffusion, as well as the CROs and other third-party contractors acting on Diffusion's behalf, is required to comply with GCP and good laboratory practice ("GLP") requirements in all of Diffusion's clinical trials, which are enforced through periodic inspections of trial sponsors, principal investigators, and trial sites. If Diffusion or any of these third parties fail to comply with applicable GCP, GLP, or other regulatory requirements, the clinical data generated in Diffusion's clinical trials may be deemed unreliable and Diffusion may be required to perform additional clinical trials to supplement or replace such data before receiving approval of a product candidate from the FDA foreign regulatory authority. Diffusion's clinical trials must also generally be conducted with product produced under cGMP regulations. Diffusion's and Diffusion's partners' compliance with these various regulations may be reviewed by regulatory inspections at any time, processes over which Diffusion we will have very little control or immediate visibility, and a failure to comply with these regulations and policies by us, Diffusion's CROs, or any of Diffusion's other third-party partners may result in significant delays in Diffusion's development programs. In addition, principal investigators for Diffusion's clinical trials may serve as scientific advisors or consultants to Diffusion from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

In addition, in order to fund or otherwise further development of Diffusion's current or future product candidates, Diffusion may collaborate with other pharmaceutical and biotechnology companies on their development and potential commercialization of those product candidates. Diffusion would face significant competition in seeking appropriate partners and whether Diffusion reaches a definitive agreement for a collaboration will depend on many factors, including, Diffusion's assessment of a partner's resources and experience, the terms and conditions of the proposed collaboration, the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; uncertainty with respect to Diffusion's ownership of Diffusion's intellectual property; and industry and market conditions generally. These types of collaborations are complex and time-consuming to negotiate and document and could ultimately result in lower returns on investment for Diffusion's stockholders than would have been achieved developing the product candidate without a partner. Further, if Diffusion were to breach Diffusion's obligations under the agreements governing any such future collaboration, Diffusion may face substantial consequences, including potential termination of the collaboration, and Diffusion's rights to Diffusion's partners' product candidates, in which Diffusion has invested substantial time and money, would be lost.

Any failure to successfully enter into and maintain the necessary relationships with CROs and Diffusion's other current and future third-party partners and collaborators could materially and adversely affect Diffusion's business, financial condition, and results of operations.

General Risks Related to the Development, Regulatory Approval, and Commercialization of Diffusion's Product Candidates if the Merger is Not Completed

Diffusion's business, financial condition, or results of operations may also be materially adversely affected by a number of general risks related to the development and regulatory approval of Diffusion's product candidates that are not specific to Diffusion's Company, including:

- Diffusion's COVID Trial, which Diffusion completed in February 2021, was conducted in Bucharest, Romania and Diffusion may in the future conduct additional clinical trials for TSC or Diffusion's other product candidates outside the U.S. In connection with an application for marketing approval, the FDA may determine not to accept data from clinical trials conducted outside of the U.S. if they determine the data presented therefrom cannot be considered valid without further inspection of the clinical trial site, are not applicable to the U.S. population and U.S. medical practice, or as a result of certain other factors. There can be no assurance that the FDA will accept any data Diffusion obtains from trials Diffusion has conducted or may in the future conduct outside the U.S.
- Diffusion faces a number of risks related to the potential for one or more of Diffusion's future product candidates to cause undesirable side effects, have other unexpected properties, contain manufacturing defects, or be subject to misuse or abuse. The occurrence of one or more of these events with respect to a product candidate or product could delay or prevent its regulatory approval, limit its commercial potential, result in additional pre- or post-approval regulatory requirements, or subject Diffusion to product liability exposure to consumers, health care providers, or others. Product liability claims could be brought in the future even if a product candidate is ultimately approved for commercial sale and manufactured in facilities licensed and regulated by the appropriate governmental authorities, and if product liability claims brought against Diffusion in the future were to be successful, Diffusion could incur substantial liability if Diffusion's insurance coverage for those claims proved to be inadequate.

- Diffusion’s employees, independent contractors, principal investigators, consultants, vendors, CROs, and other third parties we work with in the course of Diffusion’s development activities may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, during the course of their employment or other engagement with Diffusion. Any such misconduct or improper activities, whether intentional or negligent, could result in regulatory sanctions or other penalties against the Company, exclusion from federal healthcare programs such as Medicare and Medicaid, the incurrence of substantial defense costs, and serious harm to Diffusion’s reputation.

In addition, although Diffusion currently has no marketed products, in the event any of Diffusion’s product candidates are approved for marketing and commercial sale by the FDA or any other regulatory authority, Diffusion’s business, financial condition, or results of operations may be materially adversely affected by a number of general risks related to the commercialization of such products that are not specific to Diffusion’s Company, including:

- Even if Diffusion’s product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success. The degree and rate of physician and patient adoption will depend on a number of factors, including the clinical indications for which a product candidate is approved and its effectiveness compared to other therapies, cost and the availability of reimbursement and other coverage from third party payors, Diffusion’s ability to educate patients and healthcare providers regarding a new therapy, and the effectiveness of Diffusion’s sales and marketing efforts. Furthermore, Diffusion will face significant competition, often from products sold and marketed by companies with far greater resources than Diffusion, and Diffusion’s failure to effectively compete may prevent Diffusion from achieving significant market penetration.
- With respect to any such future products available only by prescription, if we are unable to achieve and maintain coverage and adequate levels of reimbursement from third party payors – including governmental health programs such as Medicare and Medicaid and private insurance companies – and access to such third-party payors’ drug formularies, the commercial success of those products may be severely hindered. If any such products do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement and, even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate, may require co-payments that patients find unacceptably high, and may vary from payor to payor, and there is no assurance that coverage and reimbursement levels necessary to achieve commercial success will be obtained.
- Any such future products candidates that we commercialize will be subject to ongoing and continued regulatory review, including rules and regulations of the FDA and similar non-U.S. governmental authorities relating to advertising, marketing and labeling (including restrictions on the promotion of off-label use), potential risk evaluation and mitigation strategy (“REMS”) requirements, routine manufacturing and other review, and required compliance with GLP. If we or a regulatory agency discovers previously unknown problems with any such product, or any facility at or process by which it is manufactured, we may face restrictions on the sale or distribution of such product or on Diffusion’s Company as a whole, including regulatory actions requiring us to modify marketing or sales materials, suspend manufacturing or ongoing trials, initiate a recall or withdraw the product from the market entirely, enter into a consent decree, or submit to other civil or criminal investigations and penalties. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market Diffusion’s product candidates, which would adversely affect Diffusion’s ability to generate revenue and achieve or maintain profitability.
- The biopharmaceutical and pharmaceutical industries are highly regulated and the potential for future legislative reform provides uncertainty and potential threats to Diffusion’s business and Diffusion’s potential future revenue and profitability of any such future products. In the U.S., there have been, and Diffusion expects there will continue to be, a number of legislative and regulatory changes to the healthcare system intended to contain or reduce the costs of medical products and medical services including those described under the heading “Diffusion Business – Government Regulation” beginning on page 183. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for Diffusion’s products once approved or additional pricing pressures. Diffusion cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, whether in the U.S. or other market territories Diffusion may pursue.

Risks Related to EIP

Risks Related to EIP's Business, Financial Position and Capital Requirements

EIP currently does not have, and may never have, any products that generate significant revenues.

EIP is a clinical stage CNS therapeutics company with a limited operating history on which to evaluate its business and prospects. EIP currently has no products that are approved for commercial sale, and it may never be able to develop a marketable product. To date, EIP has not generated any revenues from its lead product candidate, neflamapimod, or from any other product candidate. EIP cannot guarantee that neflamapimod, or any other product candidate that it may develop or acquire in the future, will ever become marketable products. EIP's limited operating history as a company makes any assessment of its future success and viability subject to significant uncertainty.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation in the U.S. and in other countries. Before the FDA and other regulatory authorities in the European Union and elsewhere will approve neflamapimod for commercialization, EIP must demonstrate that its drug satisfies rigorous standards of safety and efficacy for each of its intended uses. In order to compete effectively, EIP's drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. EIP may not achieve any of these objectives.

EIP plans to initiate a Phase 2b randomized double-blind placebo-controlled clinical study of neflamapimod in subjects with DLB by the end of the second quarter of 2023. EIP anticipates completing enrollment in the study in the first half of 2024. EIP cannot be certain that this Phase 2b trial or any future clinical development of neflamapimod will be successful, or that it will receive the regulatory approvals required to commercialize that drug candidate for any intended use, or that any future research and drug discovery programs undertaken by EIP will yield a drug candidate suitable for investigation through clinical trials. Even if EIP is able to successfully develop neflamapimod through approval and commercialization, any revenues from sales of the drug will not materialize for several years, if at all.

EIP is a clinical-stage biopharmaceutical company, and it has incurred significant losses since its inception. EIP expects its net losses to continue for the foreseeable future. EIP is not currently profitable and may never achieve or sustain profitability. EIP is unable to predict the extent of future losses or when it might become profitable, if ever.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, and become commercially viable. EIP has incurred net losses since its inception, and as of December 31, 2022, it had an accumulated deficit of approximately \$52.3 million. EIP expects to incur net losses for the foreseeable future as it incurs significant clinical development costs related to the advancement of neflamapimod. EIP has not commercialized any products and has never generated revenue from neflamapimod or any other product. In order to obtain revenues from any product candidate, EIP must succeed, either alone or in collaboration with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. EIP may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

EIP expects to incur significant additional operating losses for at least the next several years as it advances neflamapimod through clinical development, conduct clinical trials, seek regulatory approval and commercialize neflamapimod, if it is ultimately approved for marketing. The costs of advancing product candidates into each clinical phase tend to increase substantially over the clinical development process. Therefore, the total costs to advance neflamapimod to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, EIP is unable to accurately predict the timing or amount of increased expenses, or when or if it will be able to begin generating revenue from the commercialization of neflamapimod, let alone achieve or maintain profitability.

The amount of EIP's future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenues. If EIP is unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, it will not achieve profitability. Even if EIP does achieve profitability, it may not be able to sustain it, which could materially and adversely affect its business.

EIP will require additional capital to fund its operations. If EIP fails to obtain necessary financing on acceptable terms, or if at all, it may not be able to complete the development and commercialization of neflamapimod.

EIP expects to spend substantial amounts to complete the development of, seek regulatory approvals for, and commercialize neflamapimod, if it is ultimately approved for marketing. These expenditures will include costs related to the upcoming Phase 2b clinical trial of neflamapimod in DLB and costs associated with its license agreement with Vertex, under which EIP is obligated to make certain payments in connection with the achievement of specified events.

Until such time, if ever, that EIP can generate sufficient product revenue and achieve profitability, it expects to seek to finance future cash needs through equity or debt financings and/or corporate collaboration, licensing arrangements and grants. Based upon EIP's current operating plan, EIP believes that EIP's existing cash and cash equivalents and a grant from the NIA will enable EIP to fund its operating expenses and capital expenditure requirements for at least the next 12 months. EIP's estimates and expectations regarding its cash runway are based on assumptions that may prove to be incorrect, and changing circumstances could cause it to consume capital faster or in different ways than EIP currently expects. For example, EIP's planned upcoming Phase 2b trial for neflamapimod may be more expensive, time-consuming, or difficult to implement than EIP currently anticipates. Because the length of time and activities associated with the successful development of neflamapimod is highly uncertain, EIP is unable to estimate the actual funds it will require to complete research and development and ultimately commercialize its drug candidate for one or more indications.

EIP's future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the initiation, progress, timing, costs and results of a Phase 2b trial for neflamapimod in patients with DLB, as EIP has additional development plans for neflamapimod in other disease indications;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- EIP's ability to reach certain milestone events set forth in its agreement with Vertex and the timing of such achievements, triggering EIP's obligation to make applicable payments;
- the hiring of additional clinical, scientific and operational personnel to pursue EIP's development plans, as well the increased costs of internal and external resources as to support EIP's transition to a public reporting company;
- the cost and timing of securing manufacturing arrangements for clinical or commercial production;
- the cost of establishing, either internally or in collaboration with others, sales, marketing and distribution capabilities to commercialize neflamapimod, if approved;
- the cost of filing, prosecuting, enforcing, and defending EIP's patent claims and other intellectual property rights, including defending against any patent infringement actions brought by third parties against EIP;
- EIP's ability to establish collaborations with other parties on favorable terms, if at all; and
- the extent to which EIP may in-license or acquire other product candidates or technologies.

EIP may raise additional capital in the future through a variety of sources, including public or private equity offerings, debt financings, grant funding, or strategic collaborations and licensing arrangements. Adequate additional financing may not be available to EIP on acceptable terms, or at all. EIP's failure to raise capital as and when needed would have a negative effect on its financial condition and its ability to pursue its business strategy. If EIP is unable to secure additional capital in sufficient amounts or on terms acceptable to EIP, it may have to delay, scale back or discontinue its development or commercialization activities for neflamapimod. EIP might also be required to seek funds through arrangements with third parties that require it to relinquish certain of its rights to neflamapimod or otherwise agree to terms unfavorable to it.

The Phase 2b clinical study is funded by a non-dilutive grant that is subject to certain conditions for funding in subsequent years.

The Phase 2b clinical study is funded by a grant from the NIA. The funds for the study will be disbursed over the course of the study as costs are incurred. While the funds for the first year of the study have already been allocated, the awarded funds future year total cost support are subject to the availability of funds (i.e., the NIA is funded by Congress in subsequent fiscal years) and EIP's demonstration of progress in the project that is in line with the timelines provide in the grant. If such funds are no longer available or EIP fails to demonstrate such progress, EIP's ability to continue its clinical programs may be impaired and delayed, and EIP may otherwise need to seek additional financing.

EIP could be subject to audit and repayment of its non-dilutive NIA grant.

In connection with the NIA grant, EIP may be subject to routine audits by certain government agencies. As part of an audit, these agencies may review EIP's performance, cost structures and compliance with applicable laws, regulations, policies and standards and the terms and conditions of the applicable NIA grant. If any of EIP's expenditures are found to be unallowable or allocated improperly or if EIP has otherwise violated terms of such NIA grant, the expenditures may not be reimbursed and/or it may be required to repay funds already disbursed. Any audit by the NIA may result in a material adjustment to EIP's results of operations and financial condition and harm EIP's ability to operate in accordance with its business plan. Additionally, negative results in any of its planned clinical trials of neflamapimod that are funded with an NIA grant may result in EIP's failure to receive additional NIA grants to fund future clinical trials.

EIP may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because EIP has limited financial resources, it intends to focus on developing neflamapimod and future product candidates for specific indications that EIP identifies as most likely to succeed, in terms of both regulatory approval and commercialization. As a result, EIP may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. EIP's resource allocation decisions may cause EIP to fail to capitalize on viable commercial products or profitable market opportunities. Its spending on current and future research and development programs and on product candidates for specific indications may not yield any commercially viable products. If EIP does not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for EIP to retain sole development and commercialization rights to such product candidate.

EIP may be required to make significant payments to Vertex in connection with EIP's license agreement.

In August 2012, EIP entered into an Option and License Agreement with Vertex which EIP amended in April 2014 and then further amended in November 2015 (collectively, the "Vertex Agreement"). Pursuant to the terms of the Vertex Agreement, EIP acquired an exclusive license to develop and commercialize neflamapimod for the diagnosis, treatment, and prevention of Alzheimer's disease ("AD") and other CNS disorders.

Under the Vertex Agreement, EIP is subject to significant potential future obligations, including payment of development milestones and royalties on net product sales, as well as other material obligations. The Vertex Agreement sets forth specific regulatory and product approval events and the related payments that EIP would be obligated to make to Vertex if and when such events occur.

The terms of the Vertex Agreement also provide that EIP will make royalty payments to Vertex in the event aggregate net sales for a commercialized licensed product meet specified thresholds, subject to adjustment in the event of certain events, such as the absence of a valid patent claim or if fees are due to a third party for a license necessary for the development, manufacture, sale or use of a licensed product. Such royalties will be on a sliding scale as a percentage of net sales, depending on the amount of net sales in the applicable years. EIP is also obligated to make a milestone payment to Vertex upon net sales reaching a certain specified amount in any 12-month period.

The first expected milestone events concern filing of an NDA with the FDA for marketing approval of a licensed product in the U.S., or a similar filing for a non-U.S. major market. Thus, although EIP does not expect any milestone or royalty payments to be due in the immediate future, these potential obligations represent significant cash amounts that it may ultimately be obligated to pay. EIP does not know that it will have sufficient funds available to meet its obligations if and when these payments become due. The obligation to pay some or all of these milestone and royalty amounts may materially harm EIP's development efforts, as well as its overall financial condition.

The combined company will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

The combined company will incur significant legal, accounting and other expenses that EIP did not incur as a private company, including costs associated with public company reporting requirements. The combined company will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as Nasdaq rules. These laws, rules and regulations are expected to increase the combined company's legal and financial compliance costs and to make some activities more time-consuming and costly. For example, the combined company's management team will consist of a number of executive officers of EIP prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for the combined company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the combined company to attract and retain qualified individuals to serve on the combined company's board of directors or as executive officers of the combined company, which may adversely affect investor confidence in the combined company and could cause the combined company's business or stock price to suffer.

EIP's future success depends in large part on EIP's ability to retain its key employees, as well as its ability to attract, train and motivate qualified personnel. EIP may also encounter difficulties in managing its growth, which could disrupt its operations.

EIP has a small number of full and part-time employees, and it is highly dependent on the principal members of its management team, including its two co-founders, John Alam, M.D. and Sylvie Grégoire, Pharm.D. Although EIP has employment agreements or offer letters with its executive officers and certain key employees, these agreements do not prevent them from terminating their services at any time.

Competition in the biotechnology industry for skilled and experienced employees is intense, particularly in the greater Boston, Massachusetts area where EIP's headquarters is located. EIP also faces competition for the hiring of scientific and clinical personnel from universities and research institutions, many of which are near EIP's headquarters. The loss of the services of any member of EIP's senior management, clinical development or scientific staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on EIP's business, operating results and financial condition.

EIP also relies on consultants and advisors to assist it in formulating and executing its business strategy. All of EIP's consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to EIP.

As EIP continues to develop neflamapimod for the treatment of DLB, and also to expand into clinical trials for other CNS disorders, EIP expects to experience significant growth in the number of employees and the scope of its operations. This strategy will require it to recruit additional clinical development, regulatory, scientific, and technical personnel, as well as sales and marketing personnel if EIP's drug is approved. If EIP is unable to attract, retain and motivate a sufficient number of highly qualified personnel to match its growth, its ability to further develop and commercialize neflamapimod, or any future product candidates EIP may develop or acquire, will be limited.

EIP may also be required to implement and improve managerial, operational and financial systems to manage its potential growth. Due to its limited financial and personnel resources, EIP may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of EIP's operations may lead to significant costs and may divert its management and business development resources. Any inability to manage growth could delay the execution of EIP's business plans or disrupt its operations.

Consumers may sue EIP for product liability, which could result in substantial liabilities that exceed its available resources and damage its reputation.

Researching, developing, and commercializing drug products entail significant product liability risks. The use of neflamapimod or any other product candidates EIP may develop in clinical trials and the sale of any products for which it obtains marketing approval exposes it to the risk of product liability claims. Product liability claims might be brought against EIP by clinical trial participants, patients, healthcare providers, pharmaceutical distributors or others selling or otherwise coming into contact with its product candidates or future commercial products. EIP has obtained limited product liability insurance coverage for its clinical trials, which EIP believes to be reasonable given its current operations. However, EIP's insurance coverage may not reimburse EIP or may not be sufficient to reimburse it for any expenses or losses it may suffer.

Although EIP currently has limited product liability insurance that covers its clinical trials, it will need to increase and expand this coverage as it commences larger scale trials, as well as if neflamapimod is ultimately approved for commercial sale. This insurance may be extremely expensive or may not fully cover EIP's potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of neflamapimod, if it is approved. Product liability claims could have a material adverse effect on EIP's business and results of operations.

EIP's employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

EIP is exposed to the risk of fraud, misconduct or other illegal activity by its employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, European Medicines Agency ("EMA") and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities; comply with manufacturing standards EIP has established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to EIP. If EIP obtains FDA approval of any of its product candidates and begins commercializing those products in the United States, its potential exposure under such laws will increase significantly, and its costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of subject recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to EIP's reputation. EIP has adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions EIP takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against EIP, and EIP is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant fines or other sanctions.

If EIP seeks to enter into collaborative arrangements or strategic alliances for its drug candidates, but fails to enter into and maintain successful relationships, it may have to reduce or delay its drug development activities or increase its expenditures.

An important element of a biotechnology company's strategy for developing, manufacturing and commercializing its drug candidates may be to enter into strategic alliances with pharmaceutical companies or other industry participants to advance its programs and enable it to maintain its financial and operational capacity. Biotechnology companies at EIP's stage of development sometimes rely upon collaborative arrangements or strategic alliances to complete the development and commercialization of drug candidates, particularly after the Phase 2 stage of clinical testing.

To date, EIP has not entered into any collaborative arrangements or strategic alliances, and it may face significant competition in seeking such relationships. In addition, such arrangements may place the development of EIP's drug candidates outside its control, require EIP to relinquish important rights, or may otherwise be on terms unfavorable to EIP. EIP may not be able to negotiate collaborations and alliances on acceptable terms, if at all. If EIP enters into a collaborative arrangement and it proves to be unsuccessful, EIP may have to delay, or limit the size or scope of, certain of its drug development activities.

Alternatively, if EIP elects to fund drug development or research programs on its own, it will have to increase its expenditures and will need to obtain additional funding, which may not be available to EIP on acceptable terms, if at all.

EIP's business is subject to complex and evolving U.S. and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to its business practices, or monetary penalties, and otherwise may harm EIP's business.

A wide variety of provincial, state, national, and international laws and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. For example, the European Union General Data Protection Regulation ("GDPR") which became fully effective on May 25, 2018, imposes stringent data protection requirements and provides for penalties for noncompliance of up to the greater of €20 million or four percent of worldwide annual revenues. The GDPR and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. EIP is working to comply with the GDPR and other privacy and data protection laws and regulations that apply to it, and EIP anticipates needing to devote significant additional resources to complying with these laws and regulations. It is possible that the GDPR or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with EIP's current policies and practices.

EIP's actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data EIP processes or maintains, could result in regulatory fines, investigations and enforcement actions, penalties and other liabilities, claims for damages by affected individuals, and damage to EIP's reputation, any of which could materially affect its business, financial condition, results of operations and growth prospects.

EIP's internal computer systems, or those of its vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of its product development programs, compromise sensitive information related to its business or prevent it from accessing critical information, potentially exposing it to liability or otherwise adversely affecting its business.

EIP's internal computer systems and those of its current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage, interruption or data theft from computer viruses, computer hackers, malicious code, employee theft or misuse, ransomware, social engineering (including phishing attacks), denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cybersecurity incidents, which may not be immediately or ever detected, are increasing in frequency and evolving in nature. Additionally, due to geopolitical tensions related to Russia's invasion of Ukraine, the risk of cyber-attacks may be elevated.

While EIP seeks to protect its information technology systems from system failure, accident and security breach, if such an event were to occur and cause interruptions in its operations, it could result in a disruption of EIP's development programs and its business operations, whether due to a loss of its trade secrets or other proprietary information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in EIP's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. If EIP were to experience a significant cybersecurity breach of its information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. In addition, EIP's remediation efforts may not be successful. If it does not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, it could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. In addition, in response to the recent COVID-19 pandemic, a majority of EIP's workforce began to work remotely, which has continued and is now considered its normal business. This could increase EIP's cyber security risk, create data accessibility concerns, and make EIP more susceptible to communication disruption.

To the extent that any disruption or security breach were to result in a loss of, or damage to, EIP's or its third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, EIP could incur liability including litigation exposure, penalties and fines, EIP could become the subject of regulatory actions or investigations, its competitive position could be harmed and the further development and commercialization of its product candidates could be delayed. Any of the above could have a material adverse effect on EIP's business, financial condition, results of operations or prospects. While EIP maintains cyber-liability insurance (covering security and privacy matters), such insurance may not be adequate to cover any losses experienced as a result of a cybersecurity incident.

Unfavorable global economic conditions could adversely affect EIP's business, financial condition or results of operations.

EIP's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the recent COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to EIP's business, including weakened demand for its product candidates, if approved, or its ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain EIP's suppliers, possibly resulting in supply disruption. Any of the foregoing could harm EIP's business and it cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business.

U.S. federal income tax reform could adversely affect EIP's business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect EIP or holders of its common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, former President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Additionally, on December 22, 2017, former President Trump signed into law the Tax Cuts and Jobs Act of 2017 ("TCJA"), which significantly reformed the Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in EIP's common stock. Under the TCJA, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year's taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. The CARES Act modified the TCJA with respect to the TCJA's limitation on the deduction of NOLs and provided that NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminated the limitation on the deduction of NOLs to 80 percent of current year taxable income for taxable years beginning before January 1, 2021 (but reinstated the limitation for taxable years beginning after December 31, 2020). As a result of such limitations, EIP may be required to pay federal income tax in some future year notwithstanding that it had a net loss for all years in the aggregate. Future changes in tax laws could have a material adverse effect on EIP's business, cash flow, financial condition or results of operations. EIP urges investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in EIP's Common Stock.

EIP faces risks associated with increased political uncertainty.

The recent invasion of Ukraine by Russia and the sanctions, bans and other measures taken by governments, organizations and companies against Russia and certain Russian citizens in response thereto has increased the political uncertainty in Europe and has strained the relations between Russia and a significant number of governments, including the U.S. The duration and outcome of this conflict, any retaliatory actions taken by Russia and the impact on regional or global economies is unknown, but could have a material adverse effect on EIP's business, financial condition and results of its operations.

Risks Related to EIP's Product Development and Regulatory Approval

EIP is heavily dependent on the success of its lead product candidate, neflamapimod, which is still under clinical development. If neflamapimod does not receive regulatory approval or is not successfully commercialized, EIP's business will be materially harmed.

EIP has invested almost all of its efforts and financial resources to date in the development of neflamapimod for the treatment of DLB. To date, EIP has not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidate, manufactured a commercial scale product or arranged for a third party to do so on its behalf, or conducted sales and marketing activities necessary for successful product commercialization. EIP's future success is substantially dependent on its ability to successfully complete clinical development of, obtain regulatory approval for, and successfully commercialize neflamapimod for this indication and additional indications, which may never occur.

EIP expects a substantial portion of its efforts and expenditures over the next few years will be devoted to the advancement of neflamapimod. In order to be successful, EIP will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, securing manufacturing supply, building a commercial organization, and significant marketing efforts, among other requirements, before it can generate any revenues from commercial sales. EIP cannot be certain that it will be able to successfully complete any or all of these activities.

EIP has not submitted an NDA to the FDA or comparable applications to other regulatory authorities for neflamapimod, and it does not expect to be in a position to do so for several years, if ever. Significant additional clinical testing and research will be required before it can file such applications seeking approval of neflamapimod for the treatment of DLB, or in any other indications that EIP may pursue. If EIP is unable to obtain the necessary regulatory approvals for neflamapimod, it will not be able to commercialize its drug. This would materially adversely affect EIP's financial position, and EIP may not be able to generate sufficient revenue to continue its business.

The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. There is no guarantee that EIP's planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that EIP may pursue, will be successful. If EIP is ultimately unable to obtain regulatory approval for its lead product candidate on a timely basis, if at all, its business will be substantially harmed.

The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If EIP is ultimately unable to obtain regulatory approval for its lead product candidate neflamapimod on a timely basis, if at all, its business will be substantially harmed.

Clinical trials are expensive and can be difficult to design and implement. Such trials can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any stage during the clinical trial process. EIP may experience difficulties in initiating and completing the clinical trials that it intends to conduct, and EIP does not know whether such trials will enroll patients on time, need to be redesigned, or be completed on schedule, if at all. In connection with clinical trials, EIP faces significant risks, including that its product candidate may not prove to be efficacious; patients may suffer adverse effects for reasons that may or may not be related to the product candidate being tested; the results may not confirm the positive results of its earlier preclinical studies and clinical trials; and the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

In EIP's clinical studies to date, EIP has obtained positive clinical data for neflamapimod treatment in patients with DLB. Its Phase 2a data for neflamapimod demonstrated improvement vs. placebo in dementia severity and motor function. Based on the encouraging results of its Phase 2a studies, EIP plans to initiate a confirmatory, hypothesis-testing Phase 2b randomized double-blind placebo-controlled clinical study of neflamapimod in subjects with DLB by the end of the second quarter of 2023. EIP's Phase 2b trial may not be successful or the FDA may disagree with EIP's interpretation of the clinical trial data or how those data inform the design of a potentially pivotal Phase 3 clinical trial for EIP's lead indication.

Even if EIP's initial clinical trials results are confirmed in this Phase 2b clinical proof-of-concept ("POC") trial, EIP will still need to successfully complete additional clinical trials, including a Phase 3 trial, before it is prepared to submit an NDA for regulatory approval of neflamapimod in patients with DLB, assuming that the data collected from EIP's clinical trials are deemed sufficient to support the submission of an NDA. EIP cannot predict with any certainty if or when it might complete its development efforts and submit an NDA for regulatory approval of neflamapimod, or whether any such NDA will be approved by the FDA. An NDA or comparable foreign submission seeking marketing approval for neflamapimod also may not be accepted by FDA or foreign regulatory authorities due to, among other reasons, the content or formatting of the submission.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in EIP's failure to obtain regulatory approval to market neflamapimod for any of its planned indications, which would significantly harm EIP's business, results of operations, and prospects. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for a new product candidate. As a result, EIP may be required to conduct additional nonclinical studies, alter its proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which it hopes to conduct clinical trials and develop and market its products, if approved. Further, even if EIP believes the data collected from its clinical trials are promising, such data may not be sufficient to support approval by the FDA or any comparable foreign regulatory authority.

EIP has concentrated its research and development efforts on the treatment of DLB, a disease that has seen limited success in drug development. In addition, its rationale for neflamapimod in the treatment of DLB is based on a scientific understanding of the disease that may be wrong.

There have been limited efforts by biopharmaceutical and pharmaceutical companies to develop treatments for DLB and there are no therapies available for patients that have been approved with a specific indication to treat DLB. Only symptomatic therapies that are approved for other diseases, generally either AD or Parkinson's disease, are currently utilized to manage patients with DLB. In addition, many potential disease-modifying therapies have been evaluated in other neurodegenerative diseases, particularly in AD, and these have encountered challenges in their development and, as a result, only recently two disease-modifying treatments to treat AD have been approved in the United States.

EIP's approach to the treatment of DLB focuses in large part on neflamapimod's ability to inhibit the intra-cellular enzyme p38 α . The expression of p38 α is considered to be a critical contributor in the toxicity of inflammation, alpha-synuclein, amyloid-beta and tau to neurons and synapses, which EIP and other scientific experts believe leads to synaptic dysfunction. Synaptic dysfunction, specifically impaired synaptic plasticity, leads to disruption of episodic memory and is a significant event in the development and symptomatology of DLB.

Neflamapimod blocks the effects of inflammation and other stress-inducers on neurons and synapses by inhibiting p38 α . In targeting synaptic dysfunction in this manner, EIP believes neflamapimod has the potential to not only slow disease progression, but also reverse existing memory deficits in patients with DLB; that is, to both prevent further decline and improve cognitive function. In EIP's clinical studies to date, neflamapimod treatment in patients with DLB has led to statistically significant improvement in cognition, motor function, and cognition & function, which appear to be the best clinical measures of DLB.

However, EIP cannot be certain that its approach will lead to the development of approvable or marketable products. To date the only drugs approved by the FDA to treat DLB have addressed the disease's symptoms. In addition, there has never been an approval of a drug in DLB and therefore, there are no regulatory precedents for endpoints in that indication. Consequently, the FDA has a limited set of products to rely upon in evaluating neflamapimod. This could result in a longer than expected regulatory review process, increased expected development costs or the delay or prevention of commercialization of neflamapimod for the treatment of DLB.

EIP has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability.

EIP was initially formed as a Massachusetts limited liability company in 2010 and became a Delaware corporation in March 2018. Its operations to date have generally been limited to financing and staffing the company, acquiring an exclusive license to EIP's lead product candidate, neflamapimod, and advancing neflamapimod through preclinical activities and clinical trials.

EIP has not yet demonstrated, either on its own or through collaboration with third parties, an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about its future success or viability may not be as accurate as they could be if EIP had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, EIP may encounter unforeseen expenses, complications, delays and other known and unknown factors. If it is able to successfully develop neflamapimod, EIP may eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. EIP may not be successful in such a transition and, as a result, its business may be adversely affected.

As EIP continues to build its business, EIP expects that its financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond its control. Accordingly, investors should not rely upon the results of any particular quarterly or annual period as indications of EIP's future operating performance.

Safety issues with neflamapimod or with any other product candidate EIP may develop or acquire in the future, or with product candidates or approved products of third parties that are similar to EIP's product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal after approval, if any.

Results of any clinical trial EIP conducts could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Serious adverse events or undesirable side effects caused by neflamapimod, or any other product candidates EIP may develop or acquire, could cause it or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. In addition, many compounds that have initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Further, problems with product candidates or approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as neflamapimod or any future product candidates could adversely affect the development, regulatory approval and commercialization of EIP's product candidates.

To date, neflamapimod has been evaluated in 217 patients, at doses up to 750 mg twice a day, and up to 24 weeks of treatment. The adverse effects (side effects) seen in more than 5% of neflamapimod-treated patients include headache (10% in neflamapimod-treated patients vs. 5% in placebo recipients), diarrhea (10% vs. 5%), abdominal pain (6% vs. 5%), respiratory infection (5% vs. 5%), and falls (5% vs. 5%); these events were generally mild and in all but one case (a case of diarrhea and abdominal pain) did not lead to treatment discontinuation. In addition, increased levels of certain "liver enzymes" in the blood are a well-known dose-dependent side effect of p38 MAPK inhibitors. These liver enzymes, aspartate aminotransferase and alanine aminotransferase, are proteins commonly produced in the liver, the measurements of which can help doctors evaluate liver function. With neflamapimod, during 12 weeks of dosing at 250mg BID (*i.e.*, four-fold higher daily dosing than in upcoming Phase 2b trial) in 44 subjects with rheumatoid arthritis, elevations in such liver enzymes levels were noted in six subjects (14%). Additionally, in one subject (1%) participating in the Reverse-SD 24-week trial in mild AD, ALT and AST levels increased to three times the upper limit of normal.

After EIP acquired an exclusive license from Vertex to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders, EIP submitted an investigational new drug (“IND”) application, to the FDA’s Division of Neurology Products (“DNP”) in February 2015. The DNP cleared EIP’s clinical trial application in March 2015. However, in August 2015, following a standard review of the long-term animal toxicity studies, the DNP placed a partial clinical hold on Phase 2a Study 303 and any subsequent studies proposed under the IND, limiting administration of neflamapimod to doses that lead to plasma drug levels which provide at least a 10-fold safety margin to the plasma drug levels in animals that in long-term animal toxicity studies had previously led to minimal or equivocal findings in the liver, bone marrow and CNS. A partial clinical hold means that FDA suspends part of the clinical work requested under the IND (*e.g.*, a specific protocol or part of a protocol is not allowed to proceed); however, other protocols or parts of the protocol are allowed to proceed under the IND. Under DNP’s partial clinical hold that remains in effect for the neflamapimod IND, the agency limited administration of neflamapimod to doses that lead to plasma drug levels that provide a ten-fold safety margin to human subjects, based on the plasma drug levels in animals that had previously led to minimal or equivocal toxicity findings. EIP’s current understanding of plasma drug levels achieved with neflamapimod in humans means that its investigational dosing in the United States is limited by this partial clinical hold to no more than 40 mg three times daily in patients weighing 60kg (132 lbs.) or more. EIP’s upcoming Phase 2b clinical study is being conducted at 40mg three times daily (limited to patients weighing 60kg or more within the United States, and not so limited outside the US).

Our current plans across our indications do not envision surpassing this dose level, and we do not expect this partial clinical hold to impact our ongoing and planned clinical trials. With respect to the adverse effects discussed above, the patients were asymptomatic, there were no associated increases in bilirubin, and the elevations resolved with treatment discontinuation. Liver enzyme abnormalities were not observed in the Phase 2a trial of neflamapimod in DLB. However, as EIP continues the development and clinical trials of neflamapimod, treatment-related serious adverse events (“SAEs”) may arise in the future. Side effects that are deemed to be drug-related could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects in one of EIP’s clinical trials for neflamapimod in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of EIP’s product candidate in other indications. These side effects may not be appropriately recognized or managed by the treating medical staff. In addition, discovery of previously unknown class effect problems may prevent or delay clinical development and commercial approval of product candidates or result in restrictions on permissible uses after their approval. If EIP or others identify undesirable side effects caused by the mechanisms of action of a product candidate or a class of product candidates, the FDA may require EIP to conduct additional clinical trials, or to implement a Risk Evaluation and Mitigation Strategy program, or REMS program, prior to commercial approval. Alternatively, regulatory authorities may not approve the product candidate or, as a condition of approval, require specific warnings and contraindications or place certain limitations on how EIP can promote the drug. Following a potential future drug product approval, regulatory authorities might also withdraw such approval and require EIP to take its drug off the market. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of neflamapimod or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If neflamapimod, or any other product candidates EIP may develop or acquire, receives marketing approval and EIP or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “Boxed” Warning or a contraindication;
- EIP may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;

- FDA may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, and regulatory authorities in other jurisdictions may require comparable risk mitigation plans;
- EIP may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable foreign regulatory authority may require EIP to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- EIP may decide to recall such product candidates from the marketplace after they are approved;
- EIP could be sued and held liable for injury caused to individuals exposed to or taking its product candidates; and
- EIP's reputation may suffer.

Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for neflamapimod would delay EIP's commercialization prospects, substantially increase the costs of commercializing neflamapimod, and severely harm EIP's business and financial condition.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. EIP may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of neflamapimod or any other product candidates EIP may develop or acquire.

The risk of failure in drug development is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, EIP must complete nonclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical trials are expensive, difficult to design and implement and can take several years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if neflamapimod will prove to be effective or safe for any indication in humans or will receive marketing approval.

EIP may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize neflamapimod for any indication. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than EIP anticipates or for a variety of other reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that EIP is able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB or ethics committee at each clinical site to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- inability, delay or failure in identifying, recruiting, and training suitable clinical investigators;
- delay or failure in recruiting, screening, and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- delays caused by operational issues at clinical trial sites;

- changes to the clinical trial protocols and/or changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- clinical sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with Good Clinical Practices or other regulatory requirements, or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of the authorizing IND or foreign clinical trial application being placed on temporary or permanent clinical hold by the FDA or comparable foreign regulatory authority;
- lack of adequate funding to continue a clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of EIP's CROs and other third parties, or the cost of clinical trials being greater than EIP anticipated;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of neflamapimod or EIP's future product candidates for use in clinical trials or the inability to do any of the foregoing;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly;
- clinical trials of EIP's product candidates may produce negative or inconclusive results, and EIP may decide, or regulators may require it, to conduct additional nonclinical studies, clinical trials or abandon product development programs;
- the number of patients required for clinical trials of EIP's product candidates may be larger than EIP anticipates, enrollment in these clinical trials may be slower than it anticipates or participants may drop out of these clinical trials at a higher rate than it anticipates;
- EIP's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to EIP in a timely manner, or at all;
- regulators, the IRB or a Data Safety Monitoring Board if one is used for EIP's clinical trials, may require that EIP suspend or terminate its clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of EIP's product candidates or other materials necessary to conduct clinical trials of EIP's product candidates may be insufficient or inadequate;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO, and delays or failure by EIP's CMOs or EIP to make any necessary changes to such manufacturing process;
- the FDA or comparable foreign regulatory authorities may require EIP to submit additional data or impose other requirements before permitting it to initiate a clinical trial; or
- changes in governmental regulations or administrative actions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for neflamapimod or any other future product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with EIP's clinical trial design and EIP's interpretation of data from clinical trials or may change the requirements for approval even after the FDA has reviewed and commented on the design for EIP's clinical trials.

If EIP is required to conduct additional clinical trials or other nonclinical studies of neflamapimod in various disease conditions beyond those that EIP currently contemplates, if it is unable to successfully complete clinical trials of EIP's product candidates or other studies, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, EIP may:

- be delayed in obtaining marketing approval for its product candidates;
- not obtain marketing approval for its product candidates at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for its products or inhibit its ability to successfully commercialize EIP's products;
- be subject to additional post-marketing restrictions or requirements, including post-marketing testing; or
- have the product removed from the market after obtaining marketing approval.
- EIP is also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside EIP's control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on EIP's ability to enroll a sufficient number of research participants who remain in the study until its conclusion. EIP may encounter delays in enrolling, or be unable to enroll, a sufficient number of individuals to complete any of its clinical trials, and even once enrolled EIP may be unable to retain a sufficient number of participants to complete any of its trials. Subject enrollment and retention in clinical trials depends on many factors, including:

- the eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the proximity of potential subjects to clinical sites;
- the existing body of safety and efficacy data with respect to the product candidate;
- EIP's ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies;
- competing clinical trials being conducted by other companies or institutions; and
- the risk that participants enrolled in clinical trials will drop out of the trials before completion.

Furthermore, any negative results EIP may report in clinical trials may make it difficult or impossible to recruit and retain subjects in other clinical trials of that same product candidate. Delays or failures in planned enrollment or retention of clinical trial subjects may result in increased costs or program delays, which could have a harmful effect on EIP's ability to develop a product candidate or could render further development impossible.

If EIP is unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, its development programs may be adversely impacted.

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need. For example, neflamapimod received a Fast Track designation in October 2019 from the FDA for investigation as a treatment of DLB. Fast Track designation is granted by FDA, in response to a sponsor's request, upon a determination that the product candidate is intended to treat a serious or life-threatening disease or condition and has the potential to address an unmet medical need, meaning it could provide a therapeutic option for patients where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast Track designation and other available FDA programs do not change the standards for approval but may expedite the development or approval process for certain drug candidates.

Neflamapimod may not qualify for or maintain designations under this or other incentive programs under any of the FDA's existing or future programs to expedite drug development in areas of unmet medical need. EIP's inability to fully take advantage of these incentive programs may require EIP to run larger trials, incur delays, lose opportunities that may not otherwise be available to it, and incur greater expense in the development of its product candidates.

Results of preclinical studies and early clinical trials may not be indicative of results obtained in later trials. In addition, preliminary, topline and interim data from EIP's clinical trials that EIP may announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

The results of preclinical studies and early clinical trials of a product candidate, including neflamapimod, may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry, both generally and in the DLB treatment space in particular, have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Even if EIP's clinical trials for neflamapimod are completed as planned, including a future Phase 3 trial, EIP cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

In addition, from time-to-time EIP may announce or publish preliminary, topline, or interim data from its clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. EIP also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, and it may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data EIP previously published. As a result, preliminary and interim data are not necessarily predictive of final results and should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm EIP's business prospects. Accordingly, the results from the completed preclinical studies and clinical trials for EIP's product candidates may not be predictive of the results EIP may obtain in later stage trials. Its clinical trials may produce negative or inconclusive results, and EIP may decide, or regulators may require it, to conduct additional clinical trials.

Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain approval from the FDA, the EMA or other regulatory agencies for their products. Others, including regulatory agencies, may not accept or agree with EIP's assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and EIP in general.

In addition, the information EIP chooses to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Others may not agree with what EIP determines is the material or otherwise appropriate information to include in its disclosure, and any information EIP determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding neflamapimod, a future product candidate, or its business. If the interim, preliminary, or topline data that EIP reports differ from later, final or actual results, or if others, including the FDA and comparable foreign regulatory authorities, disagree with the conclusions reached, EIP's ability to obtain approval for, and commercialize our product candidates may be harmed, which could harm its business, financial condition, results of operations and prospects.

EIP relies on third parties to conduct, supervise and monitor its clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, EIP's business will be harmed.

Although EIP designs and manages its preclinical studies and clinical trials, it does not currently have the ability to conduct clinical trials for neflamapimod on its own. EIP has relied, and will continue to rely, on third parties such as contract research organizations, medical institutions, and clinical investigators to ensure the proper and timely conduct of its clinical trials. EIP's reliance on CROs for clinical development activities limits its control over these activities, but it remains responsible for ensuring that each of EIP's trials is conducted in accordance with the applicable protocol, legal and regulatory and scientific standards. EIP does not control these third parties, and they may not devote sufficient time and resources to EIP's projects, or their performance may be substandard, resulting in clinical trial delays or suspensions, delays in submission of our marketing applications or failure of a regulatory authority to accept our applications for filing. There is no assurance that the third parties EIP engages will be able to provide the functions, tests, activities or services as agreed upon, or provide them at the agreed upon price and timeline or to EIP's requisite quality standards, including due to geopolitical events, natural disasters, public health emergencies or pandemics, or poor workforce relations or human capital management.

EIP and its CROs are required to comply with the Good Laboratory Practice requirements for preclinical studies and GCP requirements for clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. If EIP or its CROs fail to comply with GCP requirements, the clinical data generated in its clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require EIP to perform additional clinical trials before approving its marketing applications. There is also no assurance these third parties will not make errors in the design, management or retention of EIP's data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, regulatory approval of current and future product candidates may be delayed, prevented or cost significantly more than expected, all of which could have a material adverse effect on EIP's business, financial condition, results of operations and prospects.

If EIP's CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to EIP's clinical protocols or regulatory requirements or for any other reason, EIP's clinical trials may be extended, delayed or terminated, and it may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that it develops. As a result, EIP's financial results and the commercial prospects for neflamapimod would be harmed, its costs could increase, and its ability to generate revenue could be delayed.

EIP has employed several different contract research organizations for clinical trial services. Although EIP believes there are numerous alternatives to provide these services, in the event that it seeks a new CRO, EIP may not be able to enter into replacement arrangements without delays or incurring additional expenses. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. Though EIP intends to carefully manage its relationships with its CROs, there can be no assurance that EIP will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on its business, financial condition and prospects.

EIP's reliance on third parties for the production of neflamapimod may result in delays in EIP's clinical trials or regulatory approvals and may impair the development and ultimate commercialization of neflamapimod, which would adversely impact EIP's business and financial position.

EIP has no manufacturing facilities and does not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. EIP currently relies on third parties for the manufacture of drug substance, the manufacture of drug product, and the packaging of drug product for clinical use. This reliance on contract manufacturers and suppliers subjects EIP to inherent uncertainties related to product safety, availability, security and cost. Holders of NDAs, or other forms of FDA approvals, or those distributing a regulated product under their own name, are ultimately responsible for compliance with manufacturing obligations even if the manufacturing is conducted by a third party.

EIP further intends to rely on third-party contract manufacturing organizations ("CMOs"), for the production of commercial supply of neflamapimod if its drug is ultimately approved. If CMOs cannot successfully manufacture drug substance and drug product for EIP's neflamapimod program, or any other product candidate that EIP may develop or acquire in the future, in conformity to its specifications and the applicable regulatory requirements, EIP will not be able to secure or maintain regulatory approval for the use of that product candidate in clinical trials, or for commercial distribution of that product candidate, if approved. Additionally, any problems EIP experiences with any such CMOs could delay the manufacturing of its product candidates, which could harm its results of operations.

All drug manufacturers and packagers are required to operate in accordance with FDA-mandated cGMPs. A failure of any of EIP's current or future contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in obtaining regulatory approval of product candidates or the ultimate launch of products based on EIP's product candidates into the market. In the event of such failure, EIP could also face fines, injunctions, civil penalties, and other sanctions. Further, if the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve a CMO's facilities for the future commercial manufacture of neflamapimod, or if it withdraws any such approval or finds deficiencies in the future, EIP may need to find alternative manufacturing facilities, which would delay its development program and significantly impact its ability to obtain regulatory approval for or commercialize neflamapimod.

If any facility of EIP's third-party drug manufacturers or suppliers were to suffer an accident or a force majeure event such as war, missile or terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of its backup generators or similar event, EIP could be materially adversely affected and any of its clinical trials could be materially delayed. Such an extended shut down may force EIP to procure a new research and development facility or another manufacturer or supplier, which could be time-consuming. During this period, EIP may be unable to receive investigational neflamapimod supplies or any other product candidates it may develop or acquire.

The planned Phase 2b clinical trial will be conducted with a drug substance (the active pharmaceutical ingredient, or "API") already manufactured in 2019 at a third-party contract manufacturer. In addition, we have sufficient drug substance available to cover the anticipated needs for Phase 3 in DLB. This drug substance was manufactured at an established commercial contract manufacturing organization that is approved for and manufactures drug both for investigational use and marketed products. We anticipate utilizing the company for clinical trials beyond the Phase 3 clinical trial in DLB, as well potentially for commercial use. However, supplies of our neflamapimod drug substance could be interrupted from time to time, and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of drug substance could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates.

We also currently rely on a third-party CMO (different than that for the API) for the manufacture of our neflamapimod drug product. We have used the same manufacturer for our neflamapimod drug product in all our clinical trials to date. If neflamapimod is ultimately approved for commercial sale, we expect to continue to rely on third-party contractors for manufacturing the drug product. Although we intend to do so prior to any commercial launch, we have not yet entered into long-term agreements for the commercial supply of either drug substance or drug product with our current manufacturing providers, or with any alternate manufacturers.

While EIP believes that there are multiple alternative sources available for manufacturing of both drug substance and drug product in its neflamapimod program, EIP may not be able to enter into replacement arrangements without delays or additional expenditures. It cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in EIP's development and commercialization efforts.

Although EIP generally has not, and does not intend to, begin a clinical trial unless it believes it has on hand, or will be able to obtain, a sufficient supply of neflamapimod to complete the clinical trial, any significant delay in the supply of neflamapimod drug substance or drug product could considerably delay conducting EIP's clinical trials and potential regulatory approval of its product candidates.

Further, third-party suppliers, manufacturers, or distributors may not perform as agreed or may terminate their agreements with EIP, including due to the effects related to geopolitical events, natural disasters, public health emergencies or pandemics, such as the COVID-19 pandemic, or force majeure events that affect their facilities or ability to perform. Any significant problem that EIP's suppliers, manufacturers, distributors or regulatory service providers experience could delay or interrupt supply of materials necessary to produce EIP's product candidates. Failure to obtain the needed quantities of EIP's product candidates could have a material and adverse effect on its business, financial condition, results of operations and prospects.

If EIP changes the manufacturers of its product candidates, it may be required to conduct comparability studies evaluating the manufacturing processes of the product candidates.

The FDA and other regulatory agencies maintain strict requirements governing the manufacturing process for prescription drug products that would apply to EIP's product candidates, if approved. For example, when a manufacturer seeks to make any change to the manufacturing process, the FDA typically requires the applicant to conduct non-clinical and, depending on the magnitude of the changes, potentially clinical comparability studies that evaluate the potential differences in the product candidates resulting from the change in the manufacturing process. If EIP were to change manufacturers of its drug substance or drug product during or after the clinical trials and regulatory approval process for neflamapimod or any of its other product candidates, EIP will be required to conduct comparability studies assessing product candidates manufactured at the new manufacturing facility. Further, manufacturing changes are generally categorized as having either a substantial, moderate, or minimal potential to adversely affect the identity, strength or quality of the drug product as they may relate to the safety or effectiveness of the product, and if a change has a substantial potential to have an adverse effect on the drug product, an applicant must submit and receive FDA approval of a prior approval supplemental ("PAS") application before the product made with the manufacturing change is distributed. Other forms of notice to FDA are also required for manufacturing changes that have a moderate or minimal potential to have an adverse effect on the drug product's safety or effectiveness. Regardless of the type of manufacturing change, the methods used and the facilities and controls used for the manufacture, processing, packaging, or holding of human drugs must comply with applicable cGMP regulations.

Delays in designing and completing a comparability study to the satisfaction of the FDA or other regulatory agencies could delay or preclude EIP's development plans and, thereby, delay EIP's ability to receive marketing approval or limit its revenue and growth, once approved. In addition, in the event that the FDA or other regulatory agencies do not accept non-clinical comparability data, EIP may need to conduct a study involving dosing of patients comparing the two products. That study may result in a delay in the approval or launch of any of its product candidates.

Any product candidate for which EIP obtains marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and EIP may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with its products, when and if any of them are approved.

If the FDA or a comparable foreign regulatory authority approves neflamapimod or any of EIP's future product candidates for marketing, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called "Phase 4 trials") and post-marketing surveillance to monitor the safety or efficacy of the product. If EIP or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant non-compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or EIP. If EIP or its third-party providers, including EIP's CMOs, fail to comply fully with applicable regulations, then EIP may be required to initiate a recall or withdrawal of its products.

EIP must also comply with requirements concerning advertising and promotion for any of its product candidates for which it obtains marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, EIP will not be able to promote any products it develops for indications or uses for which they are not approved. The FDA and other agencies closely oversee the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if EIP promotes its products beyond their approved indications, it may be subject to enforcement actions or prosecution arising from that off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Accordingly, to the extent EIP receives marketing approval for neflamapimod, EIP and its CMOs and other third-party partners will continue to expend time, money and effort in all areas of regulatory compliance, including promotional and labeling compliance, manufacturing, production, product surveillance, and quality control. If EIP is not able to comply with post-approval regulatory requirements, it could have marketing approval for any of its products withdrawn by regulatory authorities and its ability to market any future products could be limited, which could adversely affect its ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on EIP's operating results and financial condition.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of EIP's product candidates. If EIP is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained, which would adversely affect EIP's business, prospects and ability to achieve or sustain profitability.

If EIP is unable to establish sales, marketing and distribution capabilities either on its own or in collaboration with third parties, it may not be successful in commercializing neflamapimod, if approved.

EIP does not currently have any infrastructure for the sales, marketing or distribution of an approved drug product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market and successfully commercialize neflamapimod, if approved, EIP must build its sales, distribution, marketing, managerial and other non-technical capabilities, or make arrangements with third parties to perform these services.

There are significant expenses and risks involved in establishing EIP's own sales, marketing and distribution functions, including EIP's ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Alternatively, to the extent that EIP depends on third parties for such services, any revenues it receives will depend upon the efforts of those third parties, and there can be no assurance that such efforts will be successful.

If EIP is unable to establish adequate sales, marketing and distribution capabilities, either on its own or in collaboration with others, EIP will not be successful in commercializing neflamapimod, if it is ultimately approved, and it may never become profitable. EIP will be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, EIP may be unable to compete successfully against these more established companies.

Risks Related to EIP's Commercialization

EIP's business operations are subject to applicable healthcare laws and regulations. If neflamapimod is approved, EIP will also be subject to stringent regulation and ongoing regulatory obligations and restrictions, which could delay its marketing and commercialization activities and also expose it to penalties if EIP fails to comply with applicable regulations.

Although EIP does not currently have any products on the market, once it begins commercializing neflamapimod or any other future product candidates, it will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments as well as foreign governments in the jurisdictions in which EIP conducts its business. Physicians, other healthcare providers and third-party payors will play a primary role in the recommendation, prescription and use of any product candidates for which EIP obtains marketing approval. EIP's future arrangements with such third parties may expose EIP to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it markets, sells and distributes any products for which EIP obtains marketing approval. Restrictions under applicable domestic and foreign healthcare laws and regulations include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- U.S. federal false claims, false statements and civil monetary penalties laws, including the U.S. federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal healthcare programs for items and services which results from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) that imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- analogous state and foreign laws and regulations relating to healthcare fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act,” which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services (“CMS”), information related to physician payments and other transfers of value to physicians, certain advanced non-physician health care practitioners, and teaching hospitals, as well as the ownership and investment interests of physicians and their immediate family members;
- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other healthcare providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the healthcare industry;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal healthcare programs;
- HIPAA, which imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business. Efforts to ensure that EIP’s business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. Any action against EIP for violation of these laws, even if EIP successfully defends against it, could cause EIP to incur significant legal expenses and divert our management’s attention from the operation of its business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements. If the FDA or a comparable foreign regulatory authority approves any of EIP’s product candidates, EIP will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that EIP’s business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, resulting in government enforcement actions.

If EIP's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to EIP, it may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from federal healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of EIP's operations. If any of the physicians or other healthcare providers or entities with whom EIP expects to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal healthcare programs.

Even if neflamapimod or any other product candidate EIP develops receives marketing approval, it may fail to achieve the level of acceptance necessary for commercial success.

If neflamapimod, or any other product candidate EIP may develop or acquire in the future, receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, health care professionals, patients, third-party payors and others in the medical community. If EIP's drug does not achieve an adequate level of acceptance, EIP may not generate significant product revenues or become profitable. The degree of market acceptance will depend on a number of factors, including but not limited to:

- the ability to provide acceptable evidence of efficacy and potential advantages compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- EIP's ability to offer its drug for sale at competitive prices, which may be subject to regulatory control;
- the availability of third-party insurance coverage and adequate reimbursement;
- the availability of alternative treatments and the cost of a new treatment in relation to those alternatives, including any similar generic treatments;
- the relative convenience and ease of administration of a new treatment compared to alternatives, and the prevalence and severity of any side effects of a new treatment;
- the strength and effectiveness of EIP's sales, marketing and distribution capabilities, either internally or in collaboration with others;
- any restrictions on the use of EIP's product together with other medications; and
- any restrictions on the distribution of EIP's product such as those imposed under a mandatory REMS program.

If neflamapimod or any other product candidate that EIP may develop in the future does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will not achieve market acceptance, and EIP will not generate sufficient revenues to achieve profitability. Because EIP expects sales of its product candidates, if approved, to generate substantially all of its revenues for the foreseeable future, the failure of EIP's product candidates to find market acceptance would materially harm its business.

If the market opportunity for any product candidate that EIP develops is smaller than it believes, its revenue may be adversely affected and its business may suffer.

EIP intends to initially focus its product candidate development on treatments for various CNS and neurodegenerative indications. The addressable patient populations that may benefit from treatment with EIP's product candidates, if approved, are based on its estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these CNS and neurodegenerative diseases. Any regulatory approval of EIP's product candidates would be limited to the therapeutic indications examined in EIP's clinical trials and as determined by the FDA, which would not permit EIP to market its products for any other therapeutic indications not expressly reviewed and approved as safe and effective. Additionally, the potentially addressable patient population for EIP's product candidates may not ultimately be amenable to treatment with EIP's product candidates. Even if EIP receives regulatory approval for any of its product candidates, such approval could be conditioned upon label restrictions that materially limit the addressable patient population. EIP's market opportunity may also be limited by future competitor treatments that enter the market. If any of EIP's estimates prove to be inaccurate, the market opportunity for any product candidate that EIP or its strategic partners develop could be significantly diminished and have an adverse material impact on its business.

EIP faces substantial competition from other biotechnology and pharmaceutical companies, and its operating results will suffer if it fails to compete effectively.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. If neflamapimod is approved, it will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies, biopharmaceutical companies in the United States and other jurisdictions, academic institutions and governmental agencies and public and private research institutions. These organizations may have significantly greater resources than EIP does. They may also conduct similar research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with neflamapimod.

Currently, there are a limited number of companies and disease modifying approaches for DLB. However, given the potential market opportunity for the treatment of DLB and other neurodegenerative diseases, an increasing number of established pharmaceutical firms and smaller biotechnology/biopharmaceutical companies are pursuing a range of potential therapies for these diseases in various stages of clinical development. In addition to these current and potential competitors, EIP anticipates that more companies will enter the DLB market in the future. EIP's potential competitors could have significantly greater financial resources, as well as drug development, manufacturing, marketing, and sales expertise. They may also be able to develop and commercialize products that are safer, more effective, less expensive, more convenient, easier to administer, or have fewer severe effects, than existing treatments or, if it is ultimately approved, neflamapimod. Competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than EIP may obtain approval for neflamapimod, which could result in their establishing or strengthening a commercial position before EIP is able to enter the market. The highly competitive nature of the biotechnology and pharmaceutical industries, as well as the rapid technological changes in those fields, could limit EIP's ability to advance neflamapimod commercially. If EIP is unable to compete effectively, this could have a material adverse effect on its business and results of operations.

The successful commercialization of neflamapimod, or any other product candidate EIP may develop or acquire, will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for EIP's product candidates, if approved, could limit its ability to market those products and decrease its ability to generate revenue.

In the United States, the availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as neflamapimod, if it is approved. EIP's ability to achieve acceptable levels of coverage, payment, and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on EIP's ability to successfully commercialize neflamapimod and any other potential future product candidates. Assuming EIP obtains coverage for neflamapimod by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. EIP cannot be sure that coverage, payment, and reimbursement in the United States or elsewhere will be available for or any drug product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Further, if neflamapimod is approved in any jurisdictions outside of the United States, EIP may also be subject to extensive governmental price controls and other market regulations in those countries. Governments outside of the United States, particularly the countries of the European Union, tend to impose strict price controls on prescription pharmaceutical products. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, EIP may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of EIP's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, EIP's business could be harmed, possibly materially. As a result, EIP might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product and negatively impact the revenue EIP is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder EIP's ability to recoup its investment in its product candidates, even after obtaining regulatory approval.

The market for any products for which EIP may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, which are the lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. No uniform policy of coverage and reimbursement for drug products exists among third-party payors in the United States, and coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly. It will require EIP to provide scientific and clinical support for the use of its product candidates to each payor separately, with no assurance that coverage will be obtained.

In addition, efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products. As a result, those payors may not cover or provide adequate payment for neflamapimod, if it is approved. Third-party payors are also increasingly challenging the prices charged for pharmaceutical products and services. Those payors may consider a product as substitutable, and only offer to reimburse patients for the less expensive product. Even if EIP shows improved efficacy or improved convenience of administration compared to existing treatments for its target indications, pricing of existing drugs may limit the amount EIP will be able to charge for neflamapimod.

If EIP is unable to obtain adequate coverage and payment levels for its products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them, and patients may decline to purchase them. This in turn would affect EIP's ability to successfully commercialize any approved products and thereby adversely impact its profitability, results of operations, and financial condition.

Enacted and future healthcare legislation may increase the difficulty and cost for EIP to obtain marketing approval of and commercialize its product candidates, if approved, and also affect the prices it may set.

There have been, and EIP expects will continue to be, a number of legislative and regulatory proposals and changes to the healthcare systems in the United States and other jurisdictions that could affect EIP's future results of operations. In particular, a number of initiatives at the U.S. federal and state levels have aimed to reduce healthcare costs and improve the quality of healthcare. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of neflamapimod or any future product candidates EIP may develop or acquire. EIP cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If EIP is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, EIP may lose any marketing approval that it may have obtained, and it may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, healthcare, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Healthcare and Education Reconciliation Act ("ACA"), which expanded healthcare coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under federal healthcare programs. The ACA contained a number of provisions that affect coverage and reimbursement of drug products or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Since its enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA. In June 2021 the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

EIP's industry continues to face potential changes in the legal and regulatory landscape on the federal, state and international levels. Additional legislative actions to control U.S. healthcare or other costs have passed. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. There has also been increasing public and government interest in the United States with respect to specialty drug pricing practices, including proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, put in place limits and caps on pharmaceutical prices, request rebates for certain pharmaceutical products, and reform government program reimbursement methodologies for drugs. For example, in March 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price ("AMP"), for single source and innovator multiple source drugs, beginning January 1, 2024. Payment methodologies may also be subject to changes in health care legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law in August 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to appears to be leading to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry, and members of Congress continue to propose reforms for the PBM industry, all or each of which could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical product developers like EIP.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement, and to control the prices of medicinal products for human use.

EIP cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. In the United States, future laws and regulation may result in more rigorous coverage criteria and increased downward pressure on the price pharmaceutical companies may receive for any approved product. Reductions in reimbursement from Medicare or other government programs may result in similar reductions in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent EIP from being able to generate revenue, attain profitability or commercialize its product candidates. Further, if EIP or any third parties with whom it engages in the future are slow or unable to adapt to changes in existing requirements or policies, or if EIP is not able to maintain regulatory compliance, its ability to generate revenue, attain profitability, or commercialize neflamapimod or any other products for which it receives regulatory approval may be materially and adversely affected.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of EIP's business may rely, which could negatively impact EIP's business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which EIP's operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for clinical trial applications and/or marketing applications for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect EIP's business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government or slowdown shutdown occurs, it could significantly impact the ability of the FDA to timely review and process EIP's regulatory submissions, which could have a material adverse effect on EIP's business. Further, upon completion of the Merger and in EIP's operations as a public company, future government shutdowns or slowdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

EIP's business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws.

EIP's business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which EIP operates, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. EIP's business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, EIP's dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of EIP's employees, agents, contractors, or collaborators, or those of EIP's affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against EIP, its officers, or its employees, the closing down of EIP's facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of its business. Any such violations could include prohibitions on EIP's ability to offer its products in one or more countries and could materially damage EIP's reputation, its brand, its international expansion efforts, its ability to attract and retain employees, and its business, prospects, operating results, and financial condition.

Risks Related to EIP's Intellectual Property

If EIP does not adequately protect its proprietary rights, EIP may not be able to compete effectively.

EIP relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to its neflamapimod drug development program. EIP's commercial success depends on obtaining and maintaining proprietary rights in the United States and in international jurisdictions, and successfully defending these rights against third-party challenges. EIP seeks to protect its proprietary position by filing patent applications related to its neflamapimod drug development programs in the United States and in other countries.

EIP acquired an exclusive license from Vertex in 2014 to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders. This license covers know-how, preclinical and clinical data, and certain specified Vertex patent rights, including a composition of matter patent for neflamapimod that expired in 2017. EIP has thus focused its efforts on discoveries related to neflamapimod that are reflected in issued patents and patent applications covering a range of subjects, including: methods of treating patients suffering from DLB or AD, as well as methods of reducing amyloid plaque burden; methods of improving cognition and treating neurologic disorders; methods for promoting recovery of function in patients who have suffered acute neurologic injuries, including those resulting from various forms of stroke; and methods of treating patients suffering from dementia. In addition, EIP has filed patents related to formulations of neflamapimod, including pharmaceutical compositions for oral administration exhibiting desirable pharmacokinetics and processes for the manufacture thereof. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent is limited.

EIP's issued patents and patent applications remain subject to uncertainty and continued monitoring. EIP's patent applications may fail to result in issued patents with claims that provide further coverage for neflamapimod in the United States or in foreign countries. The patent prosecution process is expensive and time-consuming, and EIP may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. EIP may also fail to identify further patentable aspects of its research and development output before it is too late to obtain patent protection. There is no assurance that all potentially relevant prior art relating to EIP's patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application.

Although EIP has already obtained several issued patents and are working to expand its estate with additional patent applications, third parties may challenge its patents' validity, enforceability, or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to EIP could deprive it of rights necessary for the successful commercialization of neflamapimod, or any other product candidates it may develop. Further, if EIP encounters delays in regulatory approvals, the period of time during which it could market a product candidate under patent protection could be reduced.

The patent position of life sciences companies can often involve complex legal and factual questions and in recent years has been the subject of significant litigation. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, EIP cannot know with certainty whether it was the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions. Further, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and EIP's patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit EIP's ability to prevent others from using or commercializing similar or identical technology and products.

EIP also intends to rely on regulatory exclusivity for protection of its product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or to maintain the extent or duration of such protections that we expect for EIP's product candidates, if approved, could affect EIP's decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on its revenue or results of operations.

Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of EIP's patents, requiring it to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may also develop, seek approval for and launch generic versions of EIP's products.

There is no composition matter patent protection that covers neflamapimod. Rather, EIP's patents provide protection around either the use of neflamapimod for specific or medical indication (so called "use patents") or the administration of neflamapimod in specific manner (e.g., at a specific dose or in a specific formulation). Patents that are not around composition of matter are narrower in scope (i.e., they do not protect against development of neflamapimod in an indication other than that the patent defines), more difficult to defend against challenges against validity, and more difficult to enforce against infringement. For these reasons, some pharmaceutical companies choose not to develop and/or license compounds that are not covered by a composition of matter patent. EIP owns a patent that is issued in the US around co-crystals of neflamapimod, any of which if they were successfully developed would be afforded composition of matter patent protection under this patent.

Without patent protection for EIP's current or future product candidates, these candidates may be open to competition from other products. As a result, EIP's patent portfolio may not provide EIP with sufficient rights to exclude others from commercializing products similar or identical to EIP's.

If EIP fails to comply with its obligations under its existing license agreement with Vertex, or with any future intellectual property licenses with third parties, EIP could lose license rights that are important to its business.

EIP is party to an Option and License Agreement with Vertex, pursuant to which EIP acquired an exclusive license to develop and commercialize neflamapimod for the diagnosis, treatment, and prevention of AD and other CNS disorders. Under the terms of the Vertex Agreement, EIP must use commercially reasonable efforts during the license term to develop and obtain regulatory approval for a licensed product in specified major markets, and to promptly and effectively commercialize the licensed product once such approval is obtained. The Vertex Agreement also contains certain specified minimum diligence requirements, including making annual expenditures set forth in a development plan, and commencing a Phase 2 clinical trial of the licensed product within a specified time period.

The Vertex Agreement provides that either party may terminate the agreement if the other party is in material breach of its obligations thereunder, following a 60-day notice and cure period, or if the other party files for bankruptcy, reorganization, liquidation, receivership, or an assignment of a substantial portion of assets to creditors. The Vertex Agreement also provides that in the event EIP materially breaches any of certain specified diligence obligations as to a specific major market, Vertex's sole remedy for such breach, following the applicable notice and cure period, will be to terminate the license as to such specific major market country.

Accordingly, EIP must be diligent in meeting its obligations under the Vertex Agreement. Any uncured, material breach under the Vertex Agreement could result in the loss of certain of its rights to neflamapimod and could compromise EIP's development and commercialization efforts. This in turn would have an adverse effect on EIP's business, which could be material.

EIP may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or EIP may need to become involved in lawsuits to protect or enforce its patents, which could be costly and time consuming, as well as potentially delay or prevent the development and commercialization of its product candidates or put its patents and other proprietary rights at risk.

EIP's commercial success depends, in part, upon EIP's ability to develop, manufacture, market and sell its lead product candidate, neflamapimod, without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. While EIP is not currently subject to any pending intellectual property litigation, and is not aware of any such threatened litigation, EIP may be exposed to future litigation by third parties based on claims that its product candidates, technologies or activities infringe the intellectual property rights of others. Some claimants may have substantially greater resources than EIP does and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than it could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target EIP. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that EIP's product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

EIP may be subject to third-party claims including infringement, interference or derivation proceedings, reexamination proceedings, post-grant review and *inter partes* review before the U.S. Patent and Trademark Office, or USPTO, or similar adversarial proceedings or litigation in other jurisdictions. Even if EIP believes such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block EIP's ability to commercialize the applicable product candidate unless EIP obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. These proceedings may also result in EIP's patent claims being invalidated or narrowed in scope. In addition, a court may hold that a third-party is entitled to certain patent ownership rights instead of EIP.

As a result of patent infringement claims, or in order to avoid potential infringement claims, EIP may choose to seek, or be required to seek, a license from the third party, which may require it to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give EIP's competitors access to the same intellectual property rights. If EIP is unable to enter into a license on acceptable terms, it could be prevented from commercializing one or more of its product candidates, forced to modify such product candidates, or to cease some aspect of EIP's business operations, which could harm EIP's business significantly. In addition, if the breadth or strength of protection provided by EIP's patents and patent applications is threatened, it could dissuade companies from collaborating with EIP to license, develop or commercialize current or future product candidates.

If EIP were to initiate legal proceedings against a third party to enforce a patent covering one of its product candidates, the defendant could counterclaim that EIP's patent is invalid or unenforceable. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, EIP cannot be certain that there is no invalidating prior art of which EIP and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, EIP would lose at least part, and perhaps all, of the patent protection on its product candidates. Furthermore, EIP's patents and other intellectual property rights also will not protect its technology if competitors design around EIP's protected technology without infringing its patents or other intellectual property rights.

Finally, even if resolved in EIP's favor, litigation or other legal proceedings relating to intellectual property claims may cause EIP to incur significant expenses and could distract its technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, which could damage EIP's reputation, harm its business, and the price of its common stock could be adversely affected.

EIP may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect EIP's ability to develop, manufacture and market its product candidates.

From time to time, EIP may identify patents or applications in the same general area as its products and product candidates. EIP may determine these third-party patents are irrelevant to its business based on various factors including its interpretation of the scope of the patent claims and its interpretation of when the patent expires. If the patents are asserted against EIP, however, a court may disagree with EIP's determinations. Further, while EIP may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, EIP's determination may be incorrect, and the issuing patent may be asserted against EIP. EIP cannot guarantee that it will be able to successfully settle or otherwise resolve such infringement claims. If EIP fails in any such dispute, in addition to being forced to pay monetary damages, it may be temporarily or permanently prohibited from commercializing its product candidates. EIP might also be forced to redesign its product candidates so that it no longer infringes the third-party intellectual property rights, if such redesign is even possible. Any of these events, even if EIP were ultimately to prevail, could require it to divert substantial financial and management resources that it would otherwise be able to devote to its business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing EIP's ability to protect its product candidates.

EIP's success is heavily dependent on intellectual property, particularly patents, and obtaining and enforcing patents in its industry involves both technological complexity and legal complexity. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of EIP's patents or narrow the scope of its patent protection.

As an example, the America Invents Act ("AIA"), which was passed in September 2011, resulted in significant changes to the U.S. patent system. Pursuant to the AIA, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before EIP could therefore be awarded a patent covering an invention of EIP's even if EIP made the invention before it was made by the third party. This requires EIP to be cognizant going forward of the time from invention to filing of a patent application.

The AIA also introduced changes that provide opportunities for third parties to challenge any issued patent with the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Such changes could increase the uncertainties and costs surrounding the prosecution of EIP's patent applications and the enforcement or defense of its issued patents.

In addition, the laws of foreign countries may not protect EIP's rights to the same extent as the laws of the United States. The complexity and uncertainty of European patent laws has increased in recent years, and the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit EIP's ability to obtain new patents in the future that may be important for its business.

EIP enjoys only limited geographical protection with respect to certain patents, and it may not be able to protect its intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering EIP's product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use EIP's technologies in jurisdictions where it has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where EIP has patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with EIP's product candidates, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Although EIP intends to protect its intellectual property rights in its expected significant markets, EIP cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which EIP may wish to market its product candidates. EIP may also decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding, which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others.

The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for EIP to stop the infringement of its patents or marketing of competing products in violation of EIP's proprietary rights generally. Proceedings to enforce its patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert its efforts and attention from other aspects of EIP's business, could put EIP's patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing, and could provoke third parties to assert claims against EIP. EIP may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If EIP is forced to grant a license to any third parties with respect to any patents relevant to EIP's business, its competitive position may be impaired.

EIP's reliance on third parties requires EIP to share its trade secrets, which increases the possibility that its trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

EIP may rely on trade secrets or confidential know-how to protect various aspects of its business, especially where patent protection is believed by EIP to be of limited value. Because it relies on third parties to manufacture neflamapimod and any future product candidates, and EIP may also collaborate with third parties on the development of neflamapimod and any future product candidates, EIP must, at times, share trade secrets with such parties. EIP may also conduct joint research and development programs that require it to share trade secrets under the terms of EIP's research and development partnerships or similar agreements. Such trade secrets or confidential know-how can be difficult to protect as confidential.

To protect this type of information against disclosure or appropriation by competitors, EIP's policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with EIP prior to beginning research or disclosing proprietary information. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose EIP's confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time-consuming and unpredictable. In addition, the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

Despite EIP's efforts to protect its trade secrets, EIP's competitors may discover EIP's trade secrets, either through breach of EIP's agreements with third parties, independent development or publication of information by any of its third-party collaborators. A competitor's discovery of EIP's trade secrets could impair its competitive position and have an adverse impact on its business.

Intellectual property discovered or developed through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a manufacturing preference for U.S.-based companies. Compliance with such regulations may limit EIP's exclusive rights and limit its ability to contract with non-U.S. manufacturers.

EIP received a grant from the NIA to support its Phase 2b clinical trial for treatment in patients with DLB. Pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"), the U.S. government may have certain rights in any invention developed or reduced to practice with this funding. In addition, in the future EIP may discover, develop, acquire, or license intellectual property that has been generated through the use of U.S. government funding or grants in which the U.S. government may have certain rights pursuant to the Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require EIP to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). Such "march-in" rights would apply to new subject matter arising from the use of such government funding or grants and would not extend to pre-existing subject matter or subject matter arising from funds unrelated to the government funding or grants. If the U.S. government exercises its march-in rights in EIP's intellectual property rights that are generated through the use of U.S. government funding or grants, EIP could be required to license or sublicense intellectual property discovered or developed by it or that it licenses on terms unfavorable to EIP, and there can be no assurance that EIP would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require EIP to expend substantial resources. Should any of these events occur, it could significantly harm EIP's business, results of operations and prospects. In addition, the U.S. government requires that, in certain circumstances, any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit EIP's ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to the Combined Company

In determining whether you should approve the issuance of shares of Diffusion Common Stock and other matters related to the Merger, as the case may be, you should carefully read the following risk factors in addition to the risks described above, which will also apply to the combined company.

The combined company's stock price is expected to be volatile, and the market price of its common stock may drop following the Merger.

The market price of the combined company's common stock following the Merger could be subject to significant fluctuations following the Merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include among others:

- the ability of the combined company or its partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of the combined company or its partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- failure of any of the combined company's product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure by the combined company to maintain its existing third-party license, manufacturing and supply agreements;
- failure by the combined company or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to the combined company's product candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by its competitors;
- failure to meet or exceed financial and development projections the combined company may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by the combined company or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined company's ability to obtain intellectual property protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined company, or if they issue an adverse or misleading opinions regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of its common stock by the combined company or its stockholders in the future;
- trading volume of the combined company's common stock;
- adverse publicity relating to the combined company's markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in the combined company's financial results.

After completion of the Merger, the market price of combined company's common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors. First, the combined company will likely have relatively few shares of common stock outstanding in the "public float" since most of the shares will be held by a small number of shareholders. In addition, the shares of common stock may be sporadically or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by shareholders may disproportionately influence the price of those shares in either direction. The price for such shares could, for example, decline precipitously in the event that a large number of the shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without a material reduction in share price.

Second, the combined company will be a speculative or "risky" investment due to its lack of profits to date. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer.

Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. The combined company may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

The combined company will need to raise additional financing in the future to fund its operations, which may not be available to it on favorable terms or at all.

The combined company will require substantial additional funds to conduct the costly and time-consuming clinical efficacy trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of neflamapimod and EIP's other product candidates and future product candidates. The combined company's future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit the combined company's ability to achieve its business objectives. If the combined company raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of its common stockholders. Further, to the extent that the combined company raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, its stockholder's ownership interest in the combined company will be diluted. In addition, any debt financing may subject the combined company to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the combined company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the combined company may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Even if the combined company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the combined company or its stockholders.

An active trading market for the combined company's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for EIP's common stock. An active trading market for the combined company's shares of common stock may never develop or be sustained. If an active market for its common stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the combined company, its business, or its market, its stock price and trading volume could decline.

The trading market for the combined company's common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of the combined company's common stock after the completion of the Merger, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, the combined company will not have any control over the analysts, or the content and opinions included in their reports. The price of the combined company's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of the combined company or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

Future sales of shares by existing stockholders could cause the combined company's stock price to decline.

If existing stockholders of Diffusion and EIP sell, or indicate an intention to sell, substantial amounts of the combined company's common stock in the public market after legal and contractual restrictions on resale discussed in this proxy statement/prospectus/information statement lapse, the trading price of the common stock of the combined company could decline. Based on shares outstanding as of May 5, 2023 and shares expected to be issued at the Effective Time, the combined company is expected to have outstanding a total of approximately 9.0 million shares of common stock outstanding (prior to giving effect to the proposed Reverse Split) immediately following the Effective Time based upon the estimated Exchange Ratio of 0.1860. Approximately 4.2 million of such shares of outstanding common stock (prior to giving effect to the proposed Reverse Split) will be freely tradable, without restriction, in the public market. Approximately 1.7 million of such shares of outstanding common stock (prior to giving effect to the proposed reverse stock split) will be held by directors, executive officers of the combined company and other affiliates and will be subject to volume limitations under Rule 144 promulgated under the Securities Act and various vesting agreements. The actual number of shares that will be outstanding and freely tradeable following completion of the Merger is unknown and subject to change based on the actual Exchange Ratio and potential adjustments to the number of EIP stockholders subject to lock-up agreements, as further described under the heading. See "*The Merger Agreement — Merger Consideration and Exchange Ratio — Exchange Ratio*" beginning on page 146 and "*Agreements Related to the Merger — Lock-up Agreements*" beginning on page 166.

After completion of the Merger, the ownership of the combined company common stock will be highly concentrated, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined company stock price to decline.

Executive officers and directors of the combined company and their affiliates are expected to own or control approximately 18.9% of the outstanding shares of the combined company common stock immediately following the closing of the Merger. Certain other former stockholders of EIP are expected to own or control approximately 58.6% of the outstanding shares of the combined company common stock immediately following the closing of the Merger. Additionally, Dr. Alam and Dr. Grégoire, who are married, will hold a significant interest in the combined company's common stock on a fully diluted basis. For as long as Dr. Alam and Dr. Grégoire maintain a significant interest in the combined company, they may be in a position to affect the combined company's governance and operations. Accordingly, these stockholders will, in the aggregate, exercise substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the combined company, even if such a change of control would benefit the other stockholders of the combined company. The significant concentration of stock ownership may adversely affect the trading price of the combined company's common stock due to investors' perception that conflicts of interest may exist or arise.

The unaudited pro forma condensed combined financial statements included in this proxy statement/prospectus/information statement are presented for illustrative purposes only and may not be an indication of the combined company's actual financial condition or results of operations of future periods, or the financial condition or results of operations that would have been realized following the completion of the Merger.

The unaudited pro forma condensed combined financial statements contained in this proxy statement/prospectus/information statement are presented for illustrative purposes only and may not be an indication of the combined company's financial condition or results of operations following the Merger for several reasons. The unaudited pro forma condensed combined financial statements have been derived from the historical audited financial statements of Diffusion and EIP and certain adjustments and assumptions have been made regarding the combined company after giving effect to the Merger. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the unaudited pro forma condensed combined financial statements do not reflect all costs that are expected to be incurred by the combined company in connection with the Merger. For example, the impact of any incremental costs incurred in integrating the two companies is not reflected in the unaudited pro forma condensed combined financial statements. As a result, the actual financial condition of the combined company following the Merger may not be consistent with, or evident from, these unaudited pro forma condensed combined financial statements. The assumptions used in preparing the unaudited pro forma condensed combined financial statements may not prove to be accurate, and other factors may affect the combined company's financial condition following the Merger. For example, the Exchange Ratio reflected in this proxy statement/prospectus/information statement is preliminary. The final Exchange Ratio could differ materially from the estimated Exchange Ratio used to prepare the pro forma adjustments. The combined company's actual results and financial position after the Merger may differ materially and adversely from the unaudited pro forma financial data included in this proxy statement/prospectus/information statement. For more information, please see the section titled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 272.

If the combined company fails to attract and retain management and other key personnel, it may be unable to successfully develop or commercialize its product candidates or otherwise implement its business plan.

The biotech industry has experienced a high rate of turnover in recent years. The combined company's ability to compete in the highly competitive biopharmaceuticals industry depends upon the ability to attract, retain, and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing, and management skills and experience. The combined company may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which the combined company will compete have greater financial and other resources, different risk profiles, and a longer history in the industry. The combined company's competitors may provide higher compensation, more diverse opportunities, and/or better opportunities for career advancement. Any or all of these competing factors may limit the combined company's ability to continue to attract and retain high quality personnel, which could negatively affect its ability to successfully develop and commercialize its product candidates and to grow the business and operations as currently contemplated.

Diffusion and EIP do not anticipate that the combined company will pay any cash dividends in the foreseeable future.

The current expectation is that the combined company will retain its future earnings, if any, to fund the development and growth of the combined company's business. As a result, capital appreciation, if any, of the common stock of the combined company will be your sole source of gain, if any, for the foreseeable future.

Changes in tax law could adversely affect the combined company's business.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by Internal Revenue Service (the "IRS"), the U.S. Treasury Department, and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect the combined company or holders of its common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on the combined company's business, cash flow, financial condition, or results of operations.

Anti-takeover provisions under Delaware law could make an acquisition of the combined company more difficult and may prevent attempts by the combined company stockholders to replace or remove the combined company management.

Because the combined company will be incorporated in Delaware, it is governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of the outstanding combined company voting stock from merging or combining with the combined company. Although Diffusion and EIP believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with the combined company's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the combined company's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

If the combined company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

The combined company will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective disclosure controls and procedures and internal control over financial reporting. The combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, EIP has never been required to test its internal controls within a specified period. This will require that the combined company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. The combined company may experience difficulty in meeting these reporting requirements in a timely manner.

The combined company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. The combined company's internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, the combined company may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities.

Provisions in the combined company's corporate charter documents and under Delaware law could make an acquisition of the combined company, which may be beneficial to the combined company's stockholders, more difficult and may prevent attempts by the combined company's stockholders to replace or remove its current directors and members of management.

Provisions in the combined company's certificate of incorporation, as amended, and its amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the company that stockholders may consider favorable, including transactions in which the combined company's stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of the combined company's common stock, thereby depressing the market price of its common stock. In addition, because the combined company's board of directors is responsible for appointing the members of its management team, these provisions may frustrate or prevent any attempts by the combined company's stockholders to replace or remove its current management by making it more difficult for stockholders to replace members of the combined company's board of directors. Among other things, these provisions:

- allow the authorized number of the combined company's directors to be changed only by resolution of its board of directors;
- limit the manner in which stockholders can remove directors from the combined company's board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to the combined company's board of directors;
- limit who may call stockholder meetings and the combined company stockholders' ability to act by written consent;

- authorize the combined company's board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the combined company's board of directors; and
- require the approval of the holders of at least 2/3 of the votes that all the combined company's stockholders would be entitled to cast to amend or repeal specified provisions of the combined company's restated certificate of incorporation or for stockholders to amend or repeal the combined company's amended and restated bylaws.

Moreover, because the combined company will be incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which generally prohibits a person who, together with their affiliates and associates, owns 15% or more of a company's outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15% or more of the company's outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

The combined company's certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by its stockholders, which could discourage lawsuits against the company and its directors, officers and employees.

The combined company's restated certificate of incorporation provides that, unless the combined company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for certain proceedings, including: (1) any derivative action or proceeding brought on the combined company's behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of the combined company's directors, officers, employees or stockholders to the company or its stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of the combined company's restated certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

These exclusive-forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit the ability of the combined company's stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with the combined company or its directors, officers or employees, which may discourage such lawsuits against the combined company and its directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in the combined company's restated certificate of incorporation to be inapplicable or unenforceable in an action, the combined company may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect its business, financial condition and operating results.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus/information statement and the documents incorporated by reference into this proxy statement/prospectus/information statement contain forward-looking statements. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as neither Diffusion nor EIP can assure you that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including “anticipates,” “believes,” “continue,” “could,” “design,” “estimates,” “expects,” “intends,” “may,” “plans,” “potentially,” “predict,” “pro forma” “seeks,” “should,” “will” or the negative of these words and phrases or other variations of these words and phrases or comparable terminology.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, forward-looking statements include any statements of the plans, strategies and objectives of management for future operations, including the execution of integration and restructuring plans and the anticipated timing of filings; any statements concerning proposed new products or developments; any statements regarding future economic conditions or performance; statements of belief and any statement of assumptions underlying any of the foregoing. Forward-looking statements may also include any statements of the plans, strategies and objectives of management with respect to the approval and the closing of the Merger, Diffusion’s ability to solicit a sufficient number of proxies to approve the merger and other matters related to the closing of the Merger.

For a discussion of the factors that may cause Diffusion, EIP or the combined company’s actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risk associated with the ability of Diffusion and EIP to complete the merger and the effect of the merger on the business of Diffusion, EIP and the combined company, see the section titled “*Risk Factors*” beginning on page 36.

These forward-looking statements include, but are not limited to, statements concerning the following:

- the approval and closing of the Merger, including the timing of the Merger;
- the ability of Diffusion to obtain a sufficient number of proxies to approve the issuance of Diffusion Common Stock in the Merger and the Reverse Split;
- likelihood of the satisfaction of other conditions to the closing of the Merger and whether and when the Merger will be consummated;
- the Exchange Ratio, and relative ownership levels as of the Effective Time;
- the expected benefits of and potential value created by the Merger for the stockholders of Diffusion and EIP;
- Diffusion’s ability to control and correctly estimate its operating expenses and its expenses associated with the Merger;
- the cash balances of the combined company following the Effective Time;
- the ability of Diffusion to remain listed on Nasdaq;
- the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings;
- plans to develop and commercialize additional products;
- the attraction and retention of highly qualified personnel;
- the ability to protect and enhance the combined company’s products and intellectual property;
- any statements concerning developments and projections relating to the combined company’s competitors or industry;
- any statements concerning the combined company’s financial performance;

- any statements regarding expectations concerning Diffusion’s or EIP’s relationships and actions with third parties; and
- future regulatory, judicial and legislative changes in Diffusion’s or EIP’s industry.

You should not rely upon forward-looking statements as predictions of future events. Neither Diffusion nor EIP can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur.

In addition, statements that “Diffusion believes,” “EIP believes” and similar statements reflect the beliefs and opinions on the relevant subject of Diffusion, EIP or the combined company, as applicable. These statements are based upon information available as of the date of this proxy statement/prospectus/information statement, and while Diffusion, EIP or the combined company, as applicable, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and such statements should not be read to indicate that Diffusion, EIP or the combined company has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Diffusion, EIP or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement/prospectus/information statement are current only as of the date on which the statements were made. Except as required by law, neither Diffusion nor EIP undertakes any obligation to update publicly any forward-looking statements for any reason after the date of this proxy statement/prospectus/information statement or to conform these statements to actual results or to changes in expectations, even if new information becomes available in the future.

THE SPECIAL MEETING OF DIFFUSION STOCKHOLDERS

Date, Time and Place

The special meeting of Diffusion stockholders will be held virtually on _____, 2023 at _____ Eastern Time by means of a live webcast. Diffusion is sending this proxy statement/prospectus/information statement to its stockholders in connection with the solicitation of proxies by Diffusion's board of directors for use at the Diffusion special meeting and any adjournments or postponements of the special meeting. This proxy statement/prospectus/information statement is first being furnished to stockholders of Diffusion on or about _____, 2023.

It could become necessary to change the date, time and/or means of holding the Diffusion special meeting. If such a change is made, Diffusion will announce the change in advance, and details on how to participate will be issued by press release, posted on Diffusion's website, and filed as additional proxy materials.

Purposes of the Diffusion Special Meeting

The purposes of the Diffusion special meeting are:

1. *Proposal No. 1 (Nasdaq Listing Rules)*. To consider and vote on a proposal to approve, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), (A) the issuance of shares of Diffusion Common Stock pursuant to the Merger, which will represent more than 20% of the shares of Diffusion Common Stock outstanding immediately prior to the Merger, and (B) the change of control resulting from the Merger (the "Stock Issuance Proposal");
2. *Proposal No. 2 (Reverse Split)*. To consider and vote on a proposal to approve an amendment to the certificate of incorporation of Diffusion, as amended, the form of which is attached as *Annex B* to this proxy statement/prospectus/information statement, to effect the Reverse Split at a ratio within a range of one new share for not less than _____ and not greater than _____ shares outstanding at any time prior to December 31, 2023, the implementation and timing of which shall be subject to the discretion of Diffusion's board of directors and, if the Merger Agreement is still in effect, to be mutually agreed upon by Diffusion and EIP prior to the Effective Time, assuming both parties agree that the implementation of the Reverse Split is applicable and necessary to complete the Merger (the "Reverse Split Proposal"); and
3. *Proposal No. 3 (Postponement)*. To consider and vote on a proposal to approve a postponement or adjournment of the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposals set forth above (the "Postponement Proposal").

Diffusion will transact no other business at the Diffusion special meeting except such business as may properly be brought before the Diffusion special meeting or any adjournment or postponement thereof.

Recommendation of Diffusion's Board of Directors

- Diffusion's board of directors has determined and believes that the issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement is in the best interests of Diffusion and its stockholders and has approved such items. Diffusion's board of directors unanimously recommends that Diffusion stockholders vote "**FOR**" the Stock Issuance Proposal as described in this proxy statement/prospectus/information statement.
- Diffusion's board of directors has determined and believes that it is advisable to, and in the best interests of, Diffusion and its stockholders to adopt an amendment to the certificate of incorporation of Diffusion, to effect the Reverse Split. Diffusion's board of directors unanimously recommends that Diffusion stockholders vote "**FOR**" the Reverse Split Proposal as described in this proxy statement/prospectus/information statement; and
- Diffusion's board of directors unanimously recommends that Diffusion stockholders vote "**FOR**" a postponement or adjournment of the Diffusion special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Stock Issuance Proposal and the Reverse Split Proposal.

Record Date and Voting Power

Only holders of record of Diffusion Common Stock at the close of business on the record date, _____, 2023, are entitled to notice of, and to vote at, the Diffusion special meeting. At the close of business on the record date, _____ shares of Diffusion Common Stock were issued and outstanding. Each share of Diffusion Common Stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See the section titled “*Principal Stockholders of Diffusion*” beginning on page 291 for information regarding persons known to the management of Diffusion to be the beneficial owners of more than 5% of the outstanding shares of Diffusion Common Stock.

Voting and Revocation of Proxies

The proxy accompanying this proxy statement/prospectus/information statement is solicited on behalf of Diffusion’s board of directors for use at the Diffusion special meeting.

If you are a stockholder of record of Diffusion as of the record date referred to above, you may vote your Diffusion shares by one of the following methods:

- At the Diffusion special meeting, by registering for and joining the special meeting and following the voting instructions available on the meeting portal during the meeting.
- Vote by Internet, by going to the web address on your proxy card and following the instructions for Internet voting.
- Vote by Telephone, by dialing the phone number on your proxy card and following the instructions for telephone voting. Please have your proxy card available when you call.
- Vote by Proxy Card, by completing, signing, dating, and mailing the enclosed proxy card in the envelope provided. If you vote by Internet or telephone, please do not mail your proxy card.

The telephone and internet voting facilities will close at 11:59 p.m. Eastern Time on _____, 2023. If a Diffusion stockholder is a registered holder voting by one of those methods, please cast your votes before that time.

If your Diffusion shares are held by your broker, bank or other nominee, that is, in “street name,” the enclosed voting instruction form is sent by the institution that holds your shares. Please follow the instructions included on that voting instruction form regarding how to instruct your broker to vote your Diffusion shares. If you do not give instructions to your broker, your broker can not vote your Diffusion shares with respect to “non-routine” items, such as proposal Nos. 1 or 3, and, as a result, absent specific instructions from the beneficial owner of such shares, brokers are not empowered to vote those shares. Routine items are proposals considered routine under certain rules applicable to brokers on which your broker may vote shares held in “street name” in the absence of your voting instructions.

On the non-routine items for which you do not give your broker instructions, your shares of Diffusion Common Stock will be treated as “broker non-votes.” All of the proposals are expected to be non-routine, other than proposal No. 2 regarding the Reverse Split. Broker non-votes, if any, would have no effect on the outcome of proposal Nos. 1 or 3, but they would have the effect of votes “against” proposal No. 2.

All properly executed proxies that are not revoked will be voted at the Diffusion special meeting and at any adjournments or postponements of the Diffusion special meeting in accordance with the instructions contained in the proxy. If a holder of Diffusion Common Stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted:

- “FOR” the Stock Issuance Approval;
- “FOR” the Reverse Split Proposal; and
- “FOR” the Postponement Proposal, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the in favor of the Stock Issuance Proposal and the Reverse Split Proposal.

Diffusion stockholders of record, other than those Diffusion stockholders who have executed support agreements in connection with the Merger, may revoke their proxy at any time before it is voted by one of the following methods:

- Submitting another proper proxy with a more recent date than that of the proxy first given by following the Internet or telephone voting instructions or completing, signing, dating and returning a proxy card to Diffusion;
- Sending timely written notice of revocation to Diffusion’s General Counsel & Corporate Secretary; or
- Attending the Diffusion special meeting and voting virtually.

Attendance alone will not revoke a proxy. If a Diffusion stockholder of record or a stockholder who owns shares of Diffusion Common Stock in “street name” has instructed a broker to vote its shares of Diffusion Common Stock, the stockholder must follow directions received from its broker to change those instructions.

Required Vote

The presence, virtually or by proxy, at the Diffusion special meeting of the holders of 33.4% of the shares of Diffusion Common Stock outstanding and entitled to vote at the Diffusion special meeting is necessary to constitute a quorum at the meeting. Abstentions and broker non-votes, if any, will be counted towards a quorum.

Proposal Number	Proposal Description	Vote Required for Approval	Effect of Abstentions	Effect of Broker Non-Votes
1	Stock Issuance Proposal	FOR votes from the holders of a majority of shares present in person or represented by proxy at a meeting at which a quorum is present and entitled to vote generally on the subject matter	Against	None
2	Reverse Split Proposal	FOR votes from the holders of a majority of outstanding shares	Against	Against
3	Postponement Proposal	FOR votes from the holders of a majority of shares present in person or represented by proxy at a meeting at which a quorum is present and entitled to vote generally on the subject matter	Against	None

No proposal is conditioned on any other proposal.

As of May 5, 2023, the directors and executive officers of Diffusion owned approximately 0.2% of the outstanding shares of Diffusion Common Stock entitled to vote at the Diffusion special meeting. The directors and executive officers of Diffusion owning these shares are subject to support agreements with EIP to vote all shares of Diffusion Common Stock owned by them as of the record date in favor of the proposals described above. As of May 5, 2023, Diffusion is not aware of any affiliate of EIP owning any shares of Diffusion Common Stock entitled to vote at the Diffusion special meeting.

Solicitation of Proxies

In addition to solicitation by mail, the directors, officers, employees and agents of Diffusion may solicit proxies from Diffusion stockholders by personal interview, telephone, telegram, email or otherwise. The costs of printing and filing this proxy statement/prospectus/information statement and proxy card will be paid by Diffusion and 50% of that amount will be added to Diffusion’s net cash calculation for purposes of calculating the Exchange Ratio. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Diffusion Common Stock for the forwarding of solicitation materials to the beneficial owners of Diffusion Common Stock. Diffusion and EIP will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. Diffusion has engaged Alliance Advisors, LLC to assist in the solicitation of proxies and provide related advice and informational support, for a services fee, and the reimbursement of customary disbursements, which are not expected to exceed \$ _____ in total. In accordance with the Merger Agreement, a portion of these costs will be added to Diffusion’s net cash calculation as an adjustment in the Diffusion stockholder’s favor.

Other Matters

As of the date of this proxy statement/prospectus/information statement, Diffusion's board of directors does not know of any business to be presented at the Diffusion special meeting other than as set forth in the notice accompanying this proxy statement/prospectus/information statement. If any other matters should properly come before the Diffusion special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

Assistance and Additional Information

If you need assistance with submitting a proxy to vote your shares via the Internet, by telephone or by completing your Diffusion proxy card, or have questions regarding the Diffusion special meeting, please contact Alliance Advisors LLC, the proxy solicitor for Diffusion, at (toll-free), (call collect) or by email at

Your vote is very important regardless of the number of shares of Diffusion Common Stock that you own, and the matters to be considered at the Diffusion special meeting are of great importance to the stockholders of Diffusion. Accordingly, you are urged to read and carefully consider the information contained in this proxy statement/prospectus/information statement and promptly submit your proxy via the Internet or by telephone or complete, date, sign and promptly return the enclosed Diffusion proxy card or voting instruction form in the enclosed postage-paid envelope. If you submit your proxy via the Internet or by telephone, you do not need to return the enclosed Diffusion proxy card.

Please vote your shares via the Internet or by telephone, or sign, date and return a Diffusion proxy card or voting instruction form promptly to ensure that your shares can be represented, even if you otherwise plan to attend the Diffusion special meeting.

THE MERGER

This discussion in this section and the section titled “The Merger Agreement” beginning on page 146 describes the material aspects of the Merger and is subject to, and is qualified in its entirety by reference to, the terms of the Merger Agreement, a copy of which is attached to this proxy statement/prospectus/information statement as Annex A and is incorporated into this proxy statement/prospectus/information statement by reference. The Merger Agreement has been included as an annex hereto to provide investors with information regarding its terms. However, it is not intended to provide any other factual information about Diffusion or EIP, or their respective businesses, or the actual conduct of their respective businesses during the period prior to the consummation of the Merger. The representations, warranties and covenants contained in the Merger Agreement were made only for purposes of such agreement as of the specific dates therein, were made solely for the benefit of the respective contracting parties to those agreements, may be subject to limitations agreed upon by the contracting parties thereto instead of establishing these matters as facts, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Accordingly, the representations and warranties set forth in the Merger Agreement may not describe the actual state of affairs as of the date they were made or at any other time and investors should not rely on them as statements of fact.

You should read carefully this entire proxy statement/prospectus/information statement for a more complete understanding of the Merger and the Merger Agreement, including the Merger Agreement attached as Annex A, the opinion of Canaccord Genuity LLC, attached as Annex C, and the other documents to which you are referred herein. See the section titled “Where You Can Find More Information” beginning on page 298.

General Description

Diffusion entered into the Merger Agreement with EIP and Merger Sub, a wholly-owned subsidiary of Diffusion. Pursuant to the Merger Agreement, and upon the terms and subject to the conditions set forth in the Merger Agreement, EIP will become a wholly-owned subsidiary of Diffusion. See “*The Merger Agreement*” beginning on page 146. At the Effective Time, Diffusion will be renamed “CervoMed Inc.” and, subject to satisfying Nasdaq’s initial listing standards, expects to trade on the Nasdaq Capital Market under the symbol “CRVO.”

Merger Consideration

At the Effective Time, each issued and outstanding share of EIP Common Stock (including shares of EIP Preferred Stock that will have been converted into EIP Common Stock immediately prior to the Effective Time) will be canceled and automatically converted into the right to receive as Merger consideration a number of shares of Diffusion Common Stock equal to the Exchange Ratio. Under the Exchange Ratio formula in the Merger Agreement, immediately following the Effective Time, former EIP equity holders are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and equity holders of Diffusion are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, in each case, assuming Diffusion’s net cash (as calculated in accordance with the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million on a pro forma basis. See “*The Merger Agreement — Merger Consideration and Exchange Ratio*” beginning on page 146.

Background of the Merger

The terms of the Merger Agreement are the result of arm’s-length negotiations between Diffusion’s board of directors, the Diffusion management team and the EIP management team, under the guidance of EIP’s board of directors, along with their respective advisors. In this process, Diffusion was assisted by experienced outside financial and legal advisors in examining and evaluating potential transactions and counterparties through outreach to a variety of prospective strategic partners and investors. The following chronology is a summary of the key meetings and events leading up to the decision by Diffusion to explore strategic alternatives, the process undertaken by Diffusion to identify and evaluate prospective counterparties, and the negotiation of the Merger Agreement with EIP. This chronology does not catalogue every conversation among the respective parties, their boards of directors and management, their respective representatives, or other parties.

Diffusion is a biopharmaceutical company that has historically focused on developing therapies designed to enhance the body's ability to deliver oxygen to the areas where it is needed most. Diffusion's most advanced product candidate, TSC, has been under development as a potential treatment for a variety of indications associated with hypoxia – a serious complication of many of medicine's most intractable and difficult-to-treat conditions – for over 20 years since Diffusion LLC's founding in 2001, most recently as a potential treatment for glioblastoma multiforme brain cancer. In an effort to enhance stockholder value, Diffusion's board of directors, in consultation with management, has regularly reviewed and discussed Diffusion's clinical development strategy for TSC, its near and long-term operating and strategic goals and plans, its operations and financial performance, and overall industry conditions. From time to time, in furtherance of this strategy, Diffusion's board of directors, together with management, has considered various strategic business initiatives intended to strengthen Diffusion's business and engaged in conversations with potential counterparties, in certain cases on a confidential basis pursuant to customary, mutual non-disclosure agreements that do not include standstill provisions or "don't ask, don't waive" clauses. The types of initiatives considered have included licensing or acquiring rights to product candidates, potential opportunities for strategic partnerships and collaborations, divesting certain product candidates, and merging or combining with other companies.

On May 6, 2021, Diffusion announced it had received written notice from Nasdaq that, based on the closing bid price of Diffusion's Common Stock for the last 30 consecutive trading days, Diffusion no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Capital Market (the "Bid Price Rule"). Diffusion was provided 180 calendar days, or until November 2, 2021, to regain compliance with the Bid Price Rule.

On June 25, 2021, Diffusion's board of directors met in person for a regularly scheduled meeting at which members of management and representatives of Diffusion's legal counsel, Dechert LLP ("Dechert"), were present via teleconference. Members of management reported on Diffusion's TSC development program, anticipated cash runway, projected additional capital needs to progress TSC to a potential significant milestone such as results from a Phase 2b or Phase 3 clinical trial, and the potential timing for an additional capital raise. During the meeting, the directors also continued discussions from prior meetings of the board of directors regarding a number of identified challenges relating to the future clinical development of TSC, including, (1) the overall age of Diffusion's TSC-related intellectual property portfolio, (2) ongoing manufacturing challenges and the potential impacts thereof on drug supply for upcoming clinical studies, (3) the time and cost associated with the potential development program required to support an application for regulatory approval of TSC, (4) the amplification of these risks created by TSC being Diffusion's only product candidate in active clinical development and (5) potential difficulties obtaining the necessary funding to complete development of TSC, on acceptable terms or at all, as a result of the foregoing. Following discussion, the board of directors instructed management to proceed with Diffusion's then-ongoing development plan for TSC and to increase ordinary course business development efforts to identify early stage development assets that management believed would be complementary to TSC and had the potential to diversify and reduce the perceived risk profile of Diffusion's asset portfolio as targets for an acquisition or in-licensing, subject to the availability of sufficient funding to support such an acquisition and future development costs.

On June 30, 2021, Diffusion announced results from its TCOM Trial, the first of the three originally-planned Oxygenation Trials.

On September 9, 2021, Diffusion issued a letter to stockholders outlining recent changes to the TSC clinical development program intended to mitigate the aforementioned challenges, the design of the Oxygenation Trials, and additional data from the TCOM Trial.

On October 8, 2021, at a regularly scheduled meeting of Diffusion's board of directors, the directors discussed among other things, Diffusion's strategy for regaining compliance with the Bid Price Rule, the expected timing of data from the remaining Oxygenation Trials, the potential to address the challenges with TSC referenced above, Diffusion's cash runway and anticipated additional capital needs to complete development of TSC, and the potential benefits and costs to Diffusion and its stockholders of both (1) acquiring or in-licensing an additional early-stage asset and (2) out-licensing or identifying a partner or collaborator with whom to co-develop TSC or its other product candidate, DFN-529. Following discussion, Diffusion's board of directors instructed management to continue its focus on the acquisition of a new product candidate to broaden its pipeline and assess the anticipated impact of an acquisition on Diffusion's overall cash runway and future financing needs, as well as the availability of potential financing on acceptable terms to support the foregoing in addition to continued development of TSC.

On November 3, 2021, Diffusion announced that it received an additional written notice from Nasdaq stating that although Diffusion had not regained compliance with the Bid Price Rule by November 2, 2021, Diffusion would be provided an additional 180 calendar days, or until May 2, 2022, to regain compliance with the Bid Price Rule.

On February 7, 2022, Diffusion's board of directors approved engaging an investment bank, other than CG, to act as exclusive underwriter or agent in any securities offering (other than an at-the-market offering) by Diffusion for a period of five months.

During February and March 2022, the investment bank contacted investors on behalf of Diffusion and presented multiple offering transactions involving issuances of convertible preferred stock and common stock for consideration by the Diffusion board of directors. However, the board of directors determined that the financial terms of each of the proposed transactions were unacceptable primarily due to the expectation that Diffusion stockholders would experience a significant amount of dilution despite the amount of additional capital expected to be raised being insufficient to fund Diffusion's TSC development program through any additional significant milestones.

On each of March 14, 2022 and March 15, 2022, the Diffusion board of directors met in-person with members of management present. At the meetings, the directors discussed, among other things, (1) Diffusion's strategy for regaining compliance with the Bid Price Rule, (2) the initial design for a Phase 2 safety and efficacy study of TSC administered with standard of care to newly diagnosed GBM patients, designated Study 200-208, (3) the expansion of Diffusion's business development outreach to include additional types of transactions, such as a merger with a counterparty larger than, or of similar size, to Diffusion with a lead product candidate in a later stage of development, and (4) the criteria upon which management proposed to assess any such potential counterparties (the "Criteria"), which Criteria, as approved by the Diffusion board of directors, included the following:

- the scientific merits, stage of development, pipeline depth and adjacency to TSC, regulatory risk, anticipated near-term material inflection points such as clinical trial results, magnitude of potential clinical impact, existing standard of care and competitive differentiation, manufacturing capabilities, and projected long-term commercial potential of the counterparty's development programs;
- the potential to create a combined company with sufficient funding – through a combination of existing cash resources, committed new financing, grant funding, or otherwise – to fund its active clinical development programs through one or more significant near-term milestones, such as clinical trial results, without requiring significant post-transaction dilution to Diffusion's stockholders;
- the type, scope, and expiration of the counterparty's intellectual property protections on its lead product candidates;
- the quality and resources of the potential counterparty's third-party collaborators, if any;
- the quality of the potential counterparty's management team and board of directors, including the quality of investors attracted to date and prior leadership experience at a large pharmaceutical company and/or public company;
- the public company readiness and anticipated speed of execution with the counterparty, including the availability of audited counterparty financial statements and/or engagement of an independent registered public accounting firm;
- the counterparty's willingness to commit to continuing development of TSC following the consummation of a transaction; and
- the implied combined company ownership ascribed to Diffusion's stockholders and/or the value ascribed to Diffusion's assets relative to the foregoing factors.

Following authorization and with ongoing instruction from Diffusion's board of directors obtained at a series of meetings from March 2022 to May 2022, Diffusion management further increased its efforts to identify and begin outreach to an expanded group of potential transaction counterparties which management believed met all or a portion of the Criteria. During this period, members of Diffusion's management team contacted and held confidential discussions with six potential counterparties that were identified based on the knowledge and professional network of Diffusion's management, its board of directors and its scientific advisory board, including Party A, a privately-held biotechnology company. While discussions continued with each of these potential counterparties through the third quarter of 2022, Diffusion ultimately determined not to pursue a transaction with any of them (other than Party A as described below) due to a variety of factors applicable to one or more of the potential counterparties including, among other things, (1) Diffusion's view that there would be insufficient funding and/or prospects with the potential counterparties to obtain additional funding to support development of both TSC and the counterparties' assets without significant additional dilution to Diffusion's stockholders or at all, (2) a lack of composition of matter patent protection on certain of the potential counterparties' lead product candidates, and (3) potential regulatory challenges associated with one of the potential counterparty's proposed development plan for its lead product candidate, including historical or planned clinical trials outside of the United States.

On March 17, 2022, Diffusion's board of directors approved a proposal seeking Diffusion stockholder approval of a reverse stock split of Diffusion Common Stock in a range of 1-for-2 to 1-for-50.

On April 18, 2022 at a special meeting of Diffusion's stockholders, Diffusion's stockholders approved the reverse stock split proposal and, on the same day, Diffusion filed an amendment to its certificate of incorporation to effect the reverse stock split at a ratio of 1-for-50.

On May 4, 2022, Diffusion announced it had received written notice from Nasdaq that Diffusion had regained compliance with the Bid Price Rule after its common stock closed at a price of \$1.00 or more for 10 consecutive trading days.

On May 10, 2022, Diffusion's board of directors met via videoconference with members of Diffusion's management and representatives of Dechert present. Following discussion, the board of directors instructed management to identify and interview potential financial advisors for recommendation to the board of directors to advise it in connection with Diffusion's existing business development activities and potentially expand its outreach with the intent of identifying a potential counterparty for a merger, collaboration, acquisition or in-licensing transaction, as discussed at the meetings of board of directors on March 14-15, 2022.

Following the May 10, 2022 board meeting, members of Diffusion's management met with 11 potential financial advisors, of which eight were thoroughly evaluated for a potential engagement, including CG.

On June 14, 2022, Diffusion's board of directors met in-person with management and representatives from Dechert present. At the meeting, Diffusion's board of directors reviewed the status of the TSC development program, projected costs and timing for Study 200-208, Diffusion's resulting financing needs and projected cash runway, a freeze on new hiring pending identification and consummation of a business development or strategic transaction, and the feedback received from the potential financial advisors regarding the Company's business development and financing prospects, the consensus of which was that a reverse merger-style transaction would be the alternative most likely to maximize long-term value for Diffusion stockholders.

On June 23, 2022, Diffusion announced results from its Altitude Trial, the second of the three originally-planned Oxygenation Trials.

On July 8, 2022, the term of Diffusion's February 2022 engagement letter with the previously specified investment bank expired.

On July 12, 2022, Diffusion's board of directors met via videoconference with management and representatives of Dechert present to continue its discussion regarding the potential engagement of a financial advisor. Following a thorough review of the potential advisors with management, the board of directors authorized management to enter into an engagement letter with CG, which the parties subsequently executed on July 18, 2022. Further information regarding the engagement letter, including the consideration payable thereunder by Diffusion to CG in connection with the Merger, is described below in the section titled "*—Opinion of Diffusion's Financial Advisor.*"

On July 26, 2022, Diffusion announced the final design of Study 200-208 based on collaboration with the United States Food and Drug Administration and its intent to dose the first patient in the trial in the first quarter of 2023.

On July 29, 2022, Diffusion's board of directors met via videoconference with management and representatives of CG and Dechert present. At the meeting, the board of directors discussed, among other things, the proposed selection methodology and continued appropriateness of the Criteria for identifying potential counterparties for a strategic transaction, and the feasibility of identifying potential counterparties that would be willing to commit to funding the TSC development program and Study 200-208 following the closing of a strategic transaction. Following discussion, the board of directors instructed CG to commence outreach to potential counterparties identified by Diffusion management that might meet all or a portion of the Criteria.

During August and September 2022, as instructed by the Diffusion board of directors, CG contacted 20 privately-held biotechnology companies that Diffusion believed met all or a portion of the Criteria, each with a lead product candidate in a therapeutic area Diffusion management believed to be complementary or tangential to TSC, in order to determine their level of interest in a potential strategic transaction. However, Diffusion did not receive a proposal from any of these companies.

On August 9, 2022, Party A submitted a non-binding indication of interest regarding a proposed merger transaction involving Party A and Diffusion.

From August 9, 2022 to late September 2022, Diffusion management continued its confidential discussions with Party A, which included a variety of proposed changes to the proposed terms presented in Party A's initial proposal, including with respect to the ownership split between the stockholders of the two companies in a potential transaction, the minimum cash amount that Diffusion would be anticipated to have on a projected closing date, anticipated additional financing needs of the combined company in excess of amounts expected to be available at a projected closing date, and Party A's willingness to commit to continued development of TSC following the closing of the transaction. The parties exchanged multiple proposals and counterproposals during this time, each of which was reviewed with and, with respect to each proposal by Diffusion, approved in advance by, Diffusion's board of directors.

On August 12, 2022, Diffusion filed its Quarterly Report on Form 10-Q for the period ended June 30, 2022 announcing, among other things, (1) it had made the decision to terminate enrollment and begin winding down its ILD-DLCO Trial, the third of the three originally-planned Oxygenation Trials, in order to conserve associated spending and redirect resources, (2) its intent to increase its efforts to identify counterparties that may be interested in a potential partnership, out-license or other similar transaction involving Diffusion's TSC-related assets, in addition to Diffusion's ongoing efforts to identify merger, business combination, acquisition and other similar opportunities with counterparties believed to satisfy the Criteria, and (3) that the previously announced first quarter of 2023 anticipated initiation of Study 200-208 would be subject to the timing and outcome of Diffusion's ongoing business development processes described in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

On September 16, 2022, Diffusion's board of directors met via videoconference with Diffusion's management and representatives of CG and Dechert present. At the meeting, among other things, representatives of CG reviewed with the board of directors the potential value for Diffusion stockholders through a reverse merger combination such as the transaction being discussed with Party A relative to Diffusion continuing as a standalone company and developing TSC. The meeting participants discussed a number of risks to Diffusion of continuing on a standalone basis, including risks related to Diffusion's shallow clinical pipeline and potential difficulties obtaining sufficient financing to fund the TSC development program due to Diffusion's low market capitalization and challenging near-term market conditions. The board of directors also discussed additional factors that it believed supported the attractiveness of a reverse merger transaction, including the limited value that the marketplace appeared to assign to TSC and Diffusion's other non-cash assets as evidenced by, among other things, the depressed trading price of Diffusion Common Stock relative to the per share value of Diffusion's cash resources, Diffusion's low market capitalization, the market's reaction to Diffusion's recent clinical development announcements and Diffusion's recent inability to secure additional financing on acceptable terms.

On September 26, 2022, senior management from Party A met with Dr. Cobuzzi and Mr. Elder via videoconference to inform them that Party A intended to pursue a proposed transaction with a third-party and was no longer interested in pursuing a strategic transaction with Diffusion.

On September 28, 2022, Diffusion's board of directors met in person with members of Diffusion management present and discussed the recent termination of negotiations by Party A, the TSC development program, ongoing and renewed efforts to identify additional potential counterparties to a strategic transaction, the continued appropriateness of the Criteria, the feasibility of identifying a potential transaction in which a counterparty that meets the other Criteria would also be willing to commit to dedicating funding to the TSC development program and Study 200-208 as a term of the transaction, and the strategic alternatives most likely to enhance stockholder value. Following discussion, Diffusion's board of directors authorized CG to expand its outreach to potential counterparties on behalf of Diffusion. The outreach would include companies that were reverse merger candidates and likely to meet all or a portion of the Criteria as determined by Diffusion. Compared to the group of 20 companies contacted by CG on Diffusion's behalf in August and September 2022, the group of potential counterparties contacted would include (1) publicly-traded biotechnology companies likely to meet all or a portion of the Criteria as determined by Diffusion and (2) potential counterparties that do not have a lead product candidate complementary or tangential to TSC but otherwise meet a portion of the Criteria as determined by Diffusion.

During October 2022, in its expanded search undertaken at the instruction of the Diffusion board of directors, CG was in contact with an additional 98 biotechnology companies to determine their level of interest in a potential strategic transaction with Diffusion. Of the 98 additional companies contacted during this time, 49 expressed preliminary interest in participating in Diffusion's strategic alternative review process and 22 (including EIP) subsequently entered into a non-disclosure agreement with Diffusion, of which 21 contained a standstill with customary fall-away provisions; the remaining non-disclosure agreement contained no standstill. At the direction of Diffusion, CG requested that each such company schedule a meeting with Diffusion's management to present information regarding such company's business and, thereafter, submit a non-binding indication of interest regarding a potential strategic transaction with Diffusion no later than November 17, 2022.

On October 16, 2022, David Dobkin, in his capacity as a managing director of LifeSci Capital LLC ("LifeSci Capital"), a boutique investment bank and an affiliate of a Diffusion shareholder, LifeSci Special Opportunities Master Fund Ltd. (the "LifeSci Fund"), sent an unsolicited non-binding proposal to Diffusion, purportedly on behalf of a client, for the all-cash acquisition of all outstanding shares of Diffusion Common Stock by such client for an aggregate purchase price of approximately \$13.4 million, or \$6.58 per share of outstanding Diffusion Common Stock. The price offered in the proposal represented approximately 52% of the value of Diffusion's cash balance at September 30, 2022 of approximately \$25.9 million, as reported in Diffusion's Quarterly Report on Form 10-Q for the period then-ended, or approximately \$12.68 per share of outstanding Diffusion Common Stock, implying a negative valuation ascribed to Diffusion's non-cash assets, including TSC.

On each of October 18, 2022 and October 24, 2022, Diffusion's board of directors met via videoconference with members of Diffusion's management and representatives of CG and Dechert present to discuss the unsolicited proposal presented by LifeSci Capital, the fiduciary duties of directors and officers under Delaware law in the context of considering a potential reverse merger transaction and the status of CG's ongoing outreach to potential transaction counterparties on behalf of Diffusion.

On October 18, 2022, Diffusion and EIP entered into a mutual non-disclosure agreement in connection with discussions regarding a potential transaction, which contained a standstill with customary fall-away provisions.

On October 25, 2022, Diffusion issued a press release publicly disclosing its ongoing strategic review process, including its engagement of CG as its financial advisor.

Also on October 25, 2022, Mr. Elder, at the direction of Diffusion's board of directors, informed Mr. Dobkin that the board of directors was rejecting the proposal presented on behalf of LifeSci Capital's client due to its inadequacy, but was inviting LifeSci Capital's client to participate in Diffusion's ongoing strategic process, including by executing a non-disclosure agreement and receiving access to confidential due diligence materials. Neither Mr. Dobkin nor LifeSci Capital's client directly responded to the invitation or provided any comments or feedback on the proposed form of non-disclosure agreement Mr. Elder provided to Mr. Dobkin, which form had been provided to, and entered into by, other participants in the process.

From November 1, 2022 to November 11, 2022, Diffusion management together with representatives of CG met with members of senior management from 15 of the potential transaction counterparties, including EIP, to further discuss the parties' mutual interest in a potential transaction and present materials regarding, among other things, their respective pipelines, cash resources, available financing sources, intellectual property portfolios, and management. In parallel during this period, members of Diffusion's management, other Diffusion employees, and representatives of Diffusion engaged in preliminary technical, regulatory, financial and legal due diligence activities with representatives from all of the 15 potential counterparties.

On November 7, 2022, Mr. Dobkin, in his capacity as a portfolio manager of LifeSci Fund, submitted a letter (the "LifeSci Nomination Letter") to Diffusion seeking to nominate an alternative slate of directors for election at Diffusion's 2022 annual meeting of stockholders.

On November 14, 2022, Diffusion issued a press release in which it announced an update on its ongoing strategic review process, its receipt and rejection of the unsolicited offer from LifeSci Capital on behalf of its client, and its subsequent receipt of the LifeSci Nomination Letter from the LifeSci Fund.

From November 14, 2022 to November 18, 2022, 16 companies, including EIP on November 16, 2022 (the "Initial Proposal"), submitted non-binding indications of interest with respect to a potential strategic transaction with Diffusion based on publicly available information and preliminary discussions between Diffusion and such parties during the prior weeks, all of which contemplated a reverse triangular merger with and into a newly-created subsidiary of Diffusion, in the case of privately-held companies, or a stock-for-stock acquisition of Diffusion by the counterparty, in the case of publicly-traded companies. Among these:

- EIP's Initial Proposal (1) ascribed a valuation of \$25.5 million to Diffusion, (2) assumed Diffusion net cash at the closing of the transaction of at least \$20.0 million, resulting in implied ownership for Diffusion's stockholders of approximately 22.8% after giving effect to the transaction and (3) contemplated grant funding available to EIP at closing of the transaction of approximately \$21.0 million, none of which was yet committed. The indication of interest contemplated a seven-member board of directors for the combined company, including two directors to be appointed by Diffusion. EIP requested that Diffusion's board of directors consider making Jane Hollingsworth one of its two appointees and expressed EIP's desire that certain of the existing Diffusion employees would remain employees of the combined company, including with Dr. Cobuzzi serving as Chief Operating Officer and Mr. Elder serving as General Counsel of the combined company.
- An indication of interest from Party B, a privately-held biotechnology company, (1) ascribed a valuation of \$25.0 million to Diffusion, (2) assumed Diffusion net cash at the closing of the transaction of at least \$20.0 million and (3) contemplated additional funding available to Party B at closing of the transaction.
- The 13 other indications of interest, ascribed valuations to Diffusion ranging from \$18.5 million to \$45.0 million, and the remaining indication of interest was silent as to an implied valuation.

On November 21, 2022, Diffusion's board of directors met via videoconference with members of management and representatives of CG and Dechert present. Members of management and representatives of CG summarized the results of the expanded outreach over the past couple of months, including the receipt of 16 non-binding indications of interest. The meeting participants identified five of the 16 companies that had submitted such non-binding indications of interest for further consideration based on the Criteria. The five identified counterparties included both privately-held biotechnology companies – including Party B – and publicly-traded biotechnology companies, and each of the identified counterparties – other than Party B – had a lead product candidate targeting therapeutic areas adjacent to indications for which Diffusion was or considered developing TSC. While Diffusion thought highly of EIP's development program, Diffusion did not include EIP in this group of five recommended counterparties at the time primarily because, unlike the five identified counterparties, the grant money referenced in EIP's indication of interest was not yet committed and its existing cash resources, when combined with Diffusion's cash resources, would not be expected to fund the combined company through the announcement of results from an ongoing or upcoming clinical trial.

The board of directors, with input from management and representatives of CG and Dechert, discussed the benefits and risks of a reverse merger transaction generally and with respect to each of the five identified counterparties more specifically, including among other things as to (1) the potential benefits of a reverse merger transaction for Diffusion stockholders (including the anticipated challenges Diffusion would face in remaining a standalone company previously reviewed by Diffusion's board of directors as well as the costs and net cash that would be available for distribution to stockholders in the event of a wind-down of Diffusion), (2) the selection methodology and application of the criteria that were used to analyze each of the indications of interest received, (3) next steps in the strategic alternative review process including arranging additional meetings among management, representatives of CG and each of the five potential counterparties and (4) anticipated timing for the signing and closing of a potential strategic transaction. Following discussion, Diffusion's board of directors authorized and instructed management and CG to schedule follow-up meetings, conduct additional due diligence, and seek to negotiate with each of the five potential counterparties.

In accordance with the direction from Diffusion's board of directors, management and representatives of Diffusion continued due diligence efforts with respect to the five identified counterparties. On or about November 28, 2022, each of the five potential counterparties submitted revised non-binding indications of interest updating their respective proposals contained in their initial indications of interest. Among the revised indications of interest received from the five identified counterparties, the updated proposal from Party B reflected the most improved terms. While Party B's indication of interest retained its initial proposed valuation of \$25.0 million for Diffusion, it lowered its cash target for Diffusion from \$20.0 million to \$14.0 million and represented the largest increase in the amount of additional funding committed (from \$14.5 million to \$19.5 million to be provided by the counterparty's affiliates at the closing of the transaction). Moreover, it was the only updated proposal in which the counterparty also committed to delivering a minimum amount of net cash at the closing of the transaction.

On November 30, 2022, Diffusion's board of directors met via videoconference with members of Diffusion's management and representatives of CG and Dechert present. Mr. Elder first summarized the directors' and officers' fiduciary duties under Delaware law in the context of considering a potential reverse merger transaction. Next, members of Diffusion's management and representatives of CG provided an update on the strategic alternative review process, and the meeting participants reviewed the relative merits and risks of moving forward with each of the five potential counterparties, including as to, among other things, board and investor quality, public company readiness, ability/need to raise contingent financing and the amount of any such financing currently committed, material near-term inflection points, quality and resources of any third-party collaborators, proposed regulatory pathway, intellectual property portfolio, and anticipated ability to reach material inflection points with pro forma cash. Following discussion, Diffusion's board of directors directed management to seek to enter into a non-binding term sheet with Party B on the terms discussed with the board of directors and enter into a mutual period of exclusivity with Party B through December 31, 2022. The board of directors believed at such time that Party B best satisfied the Criteria among the identified potential counterparties and represented the best available strategic alternative for Diffusion's stockholders primarily due to perceived regulatory advantages of Party B's development strategy for its lead product candidate, the expectation that the cash resources available to the combined company at closing would be sufficient to fund a planned late stage clinical trial evaluating Party B's lead product candidate through results and the anticipated, ongoing financial and development support expected to be provided by Party B's existing investors and third-party collaborator.

On December 5, 2022, Diffusion and Party B agreed to a non-binding term sheet and entered into mutual exclusivity through December 31, 2022 to negotiate a potential transaction.

Also on December 5, 2022, Diffusion (1) filed its definitive proxy statement with respect to its 2022 annual meeting of stockholders (the "2022 Annual Meeting") and (2) issued a letter to stockholders announcing further progress in its strategic review process and urging Diffusion stockholders to vote in favor of the Diffusion board of directors' slate of nominees at the 2022 Annual Meeting rather than the dissident slate of nominees proposed by the LifeSci Fund.

From December 5, 2022 through January 15, 2023, Diffusion and Dechert, on the one hand, and Party B and its counsel engaged in mutual diligence efforts and exchanged drafts of a merger agreement.

On December 11, 2022, Diffusion's board of directors met via videoconference with members of management present and Mr. Elder reviewed the terms of a proposed settlement agreement with the LifeSci Fund. Following approval of those terms by the board of directors at the meeting, Diffusion entered into a settlement agreement with the LifeSci Fund on December 14, 2022. The settlement agreement provided that, among other things, (1) the LifeSci Fund and its affiliates would immediately and irrevocably withdraw their nominees for election as directors of Diffusion at the 2022 Annual Meeting and (2) subject to certain conditions, including the LifeSci Fund and its affiliates continuing to hold the same number of shares of Diffusion Common Stock and not breaching the terms of the settlement agreement, Diffusion would appoint one of the LifeSci Funds' nominees to Diffusion's board of directors in the future if Diffusion had not consummated any tender offer or exchange offer, merger, acquisition, business combination, reorganization, restructuring, recapitalization, sale or acquisition of material assets, or liquidation or dissolution by July 1, 2023.

On December 16, 2022, Diffusion's board of directors met in-person with members of Diffusion's management present and discussed the status of ongoing negotiations and diligence activities with Party B, Diffusion's cash forecast, Diffusion's proposed corporate strategy for 2023 in the event a strategic transaction is not completed, including continuing development of TSC on a standalone basis or a liquidation and dissolution, and potential reductions in force if and when Diffusion determined to fully pause development of TSC.

On December 22, 2022, Diffusion and Party B entered into an amendment to the non-binding term sheet between Diffusion and Party B extending the expiration of the exclusive negotiating period to January 15, 2023 to, among other things, enable Party B to finalize definitive agreements related to its funding arrangements with its existing investors and third-party collaborator.

On December 30, 2022, Diffusion held its 2022 Annual Meeting at which, among other things, each of the director nominees was re-elected.

On January 13, 2023, the Chief Executive Officer of Party B informed Dr. Cobuzzi that, following unrelated changes to its third-party collaborator's management team and financial situation, Party B no longer expected its collaborator to provide the funding to which it previously committed with respect to Party B's proposed upcoming clinical trial.

On January 18, 2023, EIP announced that the National Institute on Aging of the National Institutes of Health awarded it a grant of \$21.0 million to support EIP's proposed 160-patient Phase 2b study of neflamapimod in individuals with dementia with Lewy bodies (DLB) (the "Phase 2b DLB Study").

On January 19, 2023, Diffusion's board of directors met via videoconference with members of Diffusion's management and representatives of CG present to discuss the difficulties Party B was encountering regarding its previously committed funding, the feasibility of Diffusion continuing its start-up activities related to Study 200-208 without incurring significant additional costs, and Diffusion's proposed corporate strategy for 2023 in the event a strategic transaction is not completed, including continuing to operate on a standalone basis and developing TSC or a liquidation and dissolution of the company. With the expiration of the mutual period of exclusivity with Party B, Diffusion's board of directors discussed the possibility of re-engaging with other potential counterparties, including the four other parties identified for further consideration at the meeting of the board of directors on November 21, 2022, as well as EIP, following EIP's announcement of committed grant funding the day prior. Following discussion, the board of directors authorized and instructed management and CG to reach out to several alternative potential counterparties from among the indications of interest received in November 2022, including EIP, to explore interest with each of these parties in a strategic transaction.

From January 19, 2023 to February 9, 2023, members of Diffusion's management and representatives of CG held a series of parallel meetings and discussions with members of senior management from EIP and four other potential counterparties to further discuss the parties' mutual interest in a potential transaction. Of the four other potential counterparties, two of the counterparties informed Diffusion's management that that they were no longer interested in pursuing a strategic transaction with Diffusion. In addition, the two remaining other potential counterparties continued to lack commitments for financing that, in addition to Diffusion's net cash balance, would reasonably be expected to meet the anticipated funding requirements of their respective clinical development programs through one or more significant milestones.

During this period, with respect to EIP, Dr. Cobuzzi and Ms. Hollingsworth held a series of meetings with John Alam, MD, the Chief Executive Officer of EIP, Sylvie Gregoire, PharmD, Executive Chair of EIP, and William Tanner, Ph.D., EIP's Chief Financial Officer. The parties discussed, among other things, the design of the Phase 2b DLB Study, the pro forma budget, the cash position and cash runway of the combined company, potential additional sources of financing, the anticipated timeline for completion of EIP's audited financial statements for the years ended December 31, 2022 and 2021, a potential outline for the economic terms of a transaction, and the composition, and experience of each party's senior leadership team and potential pro forma organizational structure. The parties did not discuss the potential post-closing composition of the combined company's board of directors or management.

On January 26, 2023, Diffusion and its representatives received access to EIP's electronic data room containing due diligence materials.

On January 31, 2023, the Diffusion Board met via videoconference with members of Diffusion's management and representatives of CG and Dechert present. Following an overview of directors' and officers' fiduciary duties under Delaware law in the context of considering a potential reverse merger transaction, members of management and representatives of CG then provided an update on the strategic alternative review process, including Party B's equity financing, the outcomes of Diffusion's renewed outreach to potential counterparties, including EIP, the due diligence conducted to date by Diffusion on each of the potential counterparties, and the proposed terms previously presented by each of the potential counterparties in their non-binding indications of interest submitted in November 2022. Diffusion's management then highlighted EIP's strengths relative to the two remaining potential counterparties with respect to its satisfaction of the Criteria, including among others the perceived scientific merits and development prospects of neflamapimod and EIP's other product candidates, the expectation that the aggregate cash resources anticipated to be available at closing would be sufficient to fund the combined company through results from the Phase 2b DLB Study without significant further dilution to Diffusion's stockholders, the depth and breadth of the EIP leadership team's pharmaceutical development experience, the speed with which Diffusion believed EIP would be able to negotiate a definitive agreement and consummate a transaction, and the belief that a transaction with EIP could provide the potential for significant long-term value enhancement to Diffusion's stockholders following consummation of the Merger. Management also noted that, with the exception of EIP, each of the other potential counterparties that remained interested in doing a transaction with Diffusion lacked sufficient financing commitments for their respective clinical development programs. The board of directors discussed the merits of pursuing a transaction with EIP, including among other things (1) the attractiveness for Diffusion's stockholders of the proposed valuation relative to the potential liquidation value of Diffusion, (2) the benefits of EIP relative to the other potential counterparties and (3) the potential challenges of continuing to operate as a standalone company and the potential need to wind-down the company, resulting in less value for Diffusion's stockholders than a transaction with EIP. Following discussion, the board of directors approved and authorized Diffusion's management to negotiate and enter into a non-binding term sheet with EIP containing terms no worse than those contained in the Initial Proposal and authorized Diffusion to enter into mutual exclusivity with EIP for a period of approximately 28 days from the date the term sheet was executed.

On February 2, 2023, at the direction of Diffusion's board of directors and after consultation with representatives of CG and Dechert, Diffusion submitted a proposed non-binding term sheet to EIP for a reverse merger transaction. Among other changes from the terms set forth in the Initial Proposal, Diffusion decreased the target amount of Diffusion's net cash to be delivered at closing from \$20.0 million to \$14.0 million and increased the value ascribed to Diffusion's non-cash assets by \$6.0 million, which, despite the proposed decrease in the target cash amount, allowed Diffusion to keep as unchanged the proposed equity split for the combined company between the Diffusion stockholders and the EIP stockholders from that initially proposed by EIP in the Initial Proposal. Diffusion also requested a mutual period of exclusivity through February 28, 2022.

In the next few days, Diffusion's management, in consultation with CG and Dechert, negotiated with members of EIP's management the non-binding term sheet, including among other things, the calculation of Diffusion's net cash and whether there would be an adjustment to the Exchange Ratio for EIP's net cash. The parties did not discuss the composition of management of the combined company or who Diffusion would designate to serve on the combined company's board of directors.

On February 9, 2023, after further consultation with representatives of CG and Dechert and in accordance with the authorization and approval of Diffusion's board of directors at the board of directors' January 31, 2023 meeting, Diffusion entered into the term sheet with EIP (the "Transaction Term Sheet"), which included a period of mutual exclusivity with EIP through March 15, 2023. The Transaction Term Sheet contained a preliminary definition with respect to the calculation of Diffusion's net cash, subject to final negotiation as part of the Merger Agreement and did not include an adjustment for EIP net cash.

On February 14 and 16, 2023, Diffusion's board of directors met via videoconference with Mr. Elder present to discuss ongoing diligence activities with EIP, the status of the first draft of the definitive merger agreement, a potential reduction in force in connection with the ongoing strategic review process and Diffusion's pause of a significant portion of its TSC development activities, including initiation of Study 200-208, pending completion of the strategic review process.

On February 17, 2023, representatives of Dechert sent an initial draft of the Merger Agreement to representatives of Mintz. From February 18, 2023 to March 30, 2023, representatives of Diffusion's management and Dechert exchanged mark-ups of the Merger Agreement and related ancillary documents, including support and lock-up agreements, and participated in extensive telephonic negotiations with members of EIP's management and representatives of Mintz regarding issues raised in those documents. Among the principal issues discussed were the circumstances under which EIP could receive a termination fee or expense reimbursement upon termination of the Merger Agreement, the amount of the termination fee and the expense reimbursement cap, the terms of the forms of the support and lock-up agreements, the conditions to closing of the Merger, the calculation of Diffusion's net cash and the related calculation of the Exchange Ratio, and the circumstances under which Diffusion should be permitted to change its recommendation of the Merger or terminate the Merger Agreement in the event of an alternative proposal or intervening event.

On February 21, 2023, EIP and its representatives received access to Diffusion's electronic data room containing due diligence materials.

On February 27, 2023, representatives of Dechert sent initial drafts of a form of lock-up agreement and a form of support agreement for each of the EIP stockholders and the Diffusion stockholders, in each case, as contemplated by the Transaction Term Sheet.

On February 28, 2023, Mintz sent a revised draft of the Merger Agreement to Dechert. Among other things, the draft added provisions with respect to the treatment of EIP's convertible notes and warrants in the proposed Merger and reflected a number of changes to the representations and warranties of Diffusion and EIP, the "fiduciary-out" provisions, the closing conditions, and the termination provisions and associated remedies.

On March 8, 2023, Diffusion's board of directors met via videoconference with Mr. Elder present to discuss continuing transaction-related due diligence activities, the status of negotiations with EIP and the process anticipated to be required by Nasdaq for listing the new shares to be issued as consideration in the proposed Merger. In the context of that discussion, the board of directors noted the upcoming expiration of the parties' mutual exclusivity on March 15, 2023 and discussed extending that period. After discussion, the board of directors authorized management to extend the exclusive negotiating period with EIP by up to 14 days as deemed necessary and appropriate by management.

Also on March 8, 2023, representatives of Dechert sent a revised draft of the Merger Agreement to Mintz. Among other things, the draft added provisions with respect to the treatment of EIP's preferred stock and convertible notes in the proposed Merger and reflected a number of changes to the representations and warranties of Diffusion and EIP, the interim operating covenants of Diffusion and EIP, the "fiduciary-out" provisions, the closing conditions, the covenant to prepare the proxy statement/prospectus/information statement and the termination provisions and associated remedies.

On March 14, 2023, Diffusion and EIP entered into an amendment to the Transaction Term Sheet extending the expiration of the exclusive negotiating period through March 24, 2023.

Also on March 14, 2023, Mintz sent a revised draft of the Merger Agreement to Dechert. Among other things, the draft reflected a number of changes to the “no-shop” provisions, the closing conditions, and the termination provisions and associated remedies, including a proposed termination fee of \$765,000 payable by Diffusion and an additional right of EIP to receive expense reimbursement for termination under certain circumstances.

On March 21, 2023, Dr. Cobuzzi received an unsolicited telephone call from the Chief Executive Officer of Party B seeking to update Diffusion regarding Party B’s continued efforts to secure new financing to support its planned upcoming clinical trial and assess whether Diffusion would be interested in renewing discussions with Party B regarding a potential strategic transaction. As required under the exclusivity agreement with EIP, this outreach was communicated to EIP.

On March 23, 2023, Diffusion’s board of directors met via videoconference with Diffusion’s management and representatives of CG and Dechert present. At the meeting, the representatives of Dechert and Mr. Elder reviewed the board of directors’ fiduciary duties in the context of a potential reverse merger transaction and provided a detailed summary of the material terms of the draft Merger Agreement negotiated to date and current open issues, including issues related to EIP’s request for both a termination fee and expense reimbursement under certain circumstances, the potential benefits and risks of the proposed transaction with EIP, and the upcoming expiration of the parties’ exclusive negotiating period, following which the Diffusion board of directors agreed to reconvene on March 26, 2023 to continue its discussion.

Later on March 23, 2023, Mintz sent to Dechert a proposed extension of the exclusive negotiating period for Diffusion and EIP through March 31, 2023.

On March 24, 2023, members of Diffusion’s management, senior management of EIP, and representatives from CG, Dechert and Mintz held a series of telephone calls and videoconferences to discuss and seek to resolve the remaining open issues in the Merger Agreement, including without limitation with respect to the parties’ rights and remedies in connection with a potential termination of the Merger Agreement, but were unable to come to a mutually agreeable solution.

At 11:59 p.m. Eastern Time on March 24, 2023, the parties’ exclusive negotiating period pursuant to the Transaction Term Sheet expired.

On March 25, 2023, representatives of Dechert sent a revised draft of the Merger Agreement to representatives of Mintz and the parties continued their discussions. The changes focused on the parties’ rights and remedies in connection with a potential termination of the Merger Agreement, including among other things eliminating the ability of EIP to receive both expense reimbursement and a termination fee upon termination of the Merger Agreement regardless of the circumstances precipitating termination and accepting EIP’s ask for a termination fee of \$765,000.

On March 26, 2023, Diffusion’s board of directors met via videoconference with management and representatives of CG and Dechert present. At the meeting, the board of directors received an update from management regarding discussions and negotiations with EIP subsequent to the meeting on March 24, 2023. Among the issues discussed was the parties’ inability to reach a mutually agreeable solution with respect to the parties’ respective rights and remedies in connection with a termination of the Merger Agreement. The board of directors discussed the likelihood of reaching an acceptable compromise with EIP and whether to restart at this time conversations with other potential transaction counterparties in light of the recent expiration of Diffusion’s exclusive negotiating period with EIP considering factors, among others, EIP’s strategic fit within the criteria that the board of directors had previously outlined, Diffusion’s monthly cash burn and the significant anticipated cost and time associated with seeking negotiations with other interested parties, if any, at this time. Following discussion, Diffusion’s board of directors determined that management should continue to seek resolution with EIP rather than restarting additional outreach at this time.

On March 26, 2023, Mintz sent a revised draft of the Merger Agreement to Dechert. The draft accepted Diffusion's proposed resolution on the issues regarding termination and associated remedies.

From March 26, 2023 to March 29, 2023, the parties finalized the terms of the Merger Agreement, lock-up agreement and support agreement and related documents.

On March 28, 2023, Diffusion received an unsolicited indication of interest from Party C, a publicly-traded biotechnology company, proposing a strategic transaction between Diffusion and Party C and ascribed an implied valuation to Diffusion of less than \$10.0 million based on Party C's closing stock price the day prior. Diffusion management had previously met with representatives of and engaged in preliminary due diligence activities with respect to, Party C in November 2022, but Party C chose not to submit an indication of interest at such time due to perceived risks associated with the contested director election then anticipated at the 2022 Annual Meeting.

Also on March 28, 2023, representatives of Dechert sent a revised draft of the Merger Agreement to Mintz. Among other things, the draft reflected changes to the representations and warranties of Diffusion and EIP and the covenant to prepare the proxy statement/prospectus/information statement.

On March 29, 2023, a representative of the LifeSci Fund delivered a letter to Diffusion's board of directors which, among other things, urged Diffusion's board of directors to pursue a dissolution of Diffusion and distribution to stockholders of remaining cash in lieu of pursuing any strategic transaction alternative. Following instruction by Diffusion's board of directors, on March 31, 2023, Dechert emailed the LifeSci Fund's outside counsel on Diffusion's behalf, informing the LifeSci Fund that Diffusion believes such actions violated the Settlement Agreement. Counsel for the LifeSci Fund replied that same day that LifeSci Fund understands and will comply with its obligation under the Settlement Agreement.

Also on March 29, 2023, Diffusion's board of directors met via videoconference with members of Diffusion's management and representatives of CG and Dechert present. Dechert and Mr. Elder reviewed the board of directors' fiduciary duties under Delaware law in the context of a potential reverse merger transaction. Management then summarized for the board of directors the correspondence recently received from each of Party C and the LifeSci Fund and the alternatives offered and recommended thereby. The board of directors discussed the possibility of pursuing a transaction with Party C on the terms proposed in its indication of interest, taking into consideration among other factors the much lower valuation Party C had proposed for Diffusion relative to the valuation EIP had proposed and the extensive additional costs and other challenges associated with negotiating with a new party if EIP were to discontinue negotiations. The board of directors also discussed the letter received from the LifeSci Fund and its prior discussions regarding the relative benefits and costs of pursuing a strategic transaction like the Merger relative to a liquidation and dissolution of Diffusion. Dr. Cobuzzi also noted that a liquidation analysis prepared by management was an element of the financial analysis that would be presented by representatives of CG later in the meeting. Referencing the copy of the draft Merger Agreement that had been provided to the board of directors in advance of the meeting, representatives of Dechert and Mr. Elder provided a summary of the revisions to the draft Merger Agreement from the draft previously reviewed in detail at the meeting of board of directors on March 23, 2023, including the proposed resolution of issues regarding the parties' rights and remedies in connection with a termination of the Merger Agreement. In the context of those summaries, Dr. Cobuzzi reminded the board of directors of EIP's proposed governance arrangements for the combined company and noted that Ms. Hollingsworth, Dr. Cobuzzi and Mr. Elder would be willing to continue with the combined company if the board of directors approved a transaction. Following that review, representatives of CG reviewed CG's financial analysis of the proposed transaction with EIP and, following discussion with the directors, delivered to the board of directors CG's oral opinion, which was subsequently confirmed by delivery of a written opinion dated March 29, 2023, to the effect that, as of such date and based upon and subject to the assumptions, qualifications and limitations set forth in its written opinion, the Exchange Ratio (as defined in the Merger Agreement) pursuant to the Merger Agreement was fair, from a financial point of view, to Diffusion. For further information on the opinion of CG, please see below the section titled "*—Opinion of Diffusion's Financial Advisor.*" Following a lengthy and detailed discussion, including all of the factors set forth in the section titled "*—Diffusion Reasons for the Merger and Stock Issuance*" below, including among others the potential conflict of interest created by the fact that Diffusion's executive officers and directors have financial or other interests in the Merger that may be different from, or in addition to, those of other stockholders, the board of directors unanimously (1) determined that the Merger and other transactions contemplated by the Merger Agreement are advisable and in the best interests of Diffusion and its stockholders, (2) approved and declared advisable the Merger Agreement, the Merger, the forms of lock-up and support agreements, and the other transactions contemplated by the Merger Agreement, and (3) resolved to recommend that Diffusion's stockholders approve the issuance of shares of Diffusion common stock to EIP securityholders in the Merger and the Reverse Split if deemed necessary. The board of directors authorized and instructed management to execute the Merger Agreement, subject to the delivery and confirmatory review of each parties' final disclosure schedules to the Merger Agreement.

In the evening of March 29, 2023 and the early morning of March 30, 2023, Mintz and Dechert held a series of telephone calls and other communications to finalize the draft documentation in connection with the Merger.

Later in the morning on March 30, 2023, Diffusion, EIP and Merger Sub entered into the Merger Agreement and the applicable parties entered into the support agreements and the lock-up agreements. Later that morning, promptly following the execution of the Merger Agreement and prior to the commencement of trading on the Nasdaq Capital Market, Diffusion and EIP issued a joint press release announcing the Merger Agreement and related documents.

Diffusion Reasons for the Merger

In reaching its decision to approve entering into the Merger Agreement and recommending the approval of the issuance of shares of Diffusion Common Stock in the Merger by the Diffusion stockholders, Diffusion's board of directors consulted with management and Diffusion's financial and legal advisors and considered a variety of factors, including among others, the following (which are not in any relative order of importance and all of which Diffusion's board of directors viewed as supporting its decision to approve the proposed transactions with EIP):

- the historical and current information concerning Diffusion's business, financial performance, financial condition, including Diffusion's cash position, operations, management and competitive position, the prospects of Diffusion and its product candidate, the nature of the biotechnology industry generally, including financial projections of Diffusion under various scenarios and its short- and long-term strategic objectives and the related risks and the belief that the combination of Diffusion's and EIP's businesses would create more value for Diffusion stockholders in the long-term than Diffusion could create as an independent, stand-alone company;
- that Diffusion's board of directors and its financial and legal advisors undertook a comprehensive and thorough process of reviewing and analyzing potential strategic transactions, including the acquisition of new assets or companies, and reverse mergers to identify the opportunity that would, in the Diffusion board of directors' opinion, create the most value for Diffusion's stockholders, as well as a liquidation of Diffusion and the distribution to its stockholders of its remaining cash after the payment of or setting aside for the payment of Diffusion's obligations in a liquidation scenario;
- the Diffusion board of directors' belief, based in part on the judgment, advice and analysis of Diffusion management with respect to the potential strategic, financial and operational benefits of the Merger (which judgment, advice and analysis was informed in part by the business, technical, financial, accounting, intellectual property and legal due diligence investigation performed by Diffusion with respect to EIP), that the Merger is more favorable to Diffusion's stockholders than the potential value that might have resulted from other strategic options available to Diffusion;
- the Diffusion board of directors' review with the management of Diffusion the current development plans of EIP's lead drug candidate neflamapimod to confirm the likelihood that the combined company would possess sufficient resources, or have access to sufficient resources, to allow the management team to focus on its plans for the continued development of EIP's product pipeline, including the possibility that the combined company would be able to take advantage of the potential benefits resulting from the combination of Diffusion's SEC registration and Nasdaq listing with EIP's business to raise additional funds in the future;
- the strength of the balance sheet of the combined company, which would include the cash that Diffusion currently holds, plus potential access to an additional \$21.0 million in funding from EIP's grant from the NIA;

- the benefits that Diffusion and its advisors were able to obtain during its negotiations with EIP, including the favorable additions to the calculation of Diffusion’s net cash for purposes of calculating the Exchange Ratio and generally improving the contract terms relating to transaction certainty, and the Diffusion board of directors’ belief that there was no assurance that a more favorable strategic opportunity would arise later or through any alternative transaction, and the terms and consideration reflected in the Merger Agreement was the best transaction that could be obtained by Diffusion stockholders from EIP at the time;
 - that the combined company is expected to be led by an experienced senior management team and a board of directors with representation from each of the current boards of directors of Diffusion and EIP;
 - the financial analysis completed by Diffusion management;
 - the oral opinion of CG rendered to Diffusion’s board of directors on March 29, 2023 (which was subsequently confirmed in writing by delivery of CG’s written opinion dated March 29, 2023), to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written opinion, the Exchange Ratio pursuant to the Merger Agreement was fair, from a financial point of view, to Diffusion; and
 - the Diffusion board of directors’ belief that the Merger would provide existing Diffusion stockholders a significant opportunity to participate in the potential growth of the combined company following the Merger;
 - that Diffusion’s board of directors reviewed and considered the terms of the Merger Agreement, including the parties’ respective representations, warranties and covenants, and the conditions to their respective obligations to consummate the Merger, the issuance of shares of Diffusion Common Stock and the other transactions contemplated by the Merger Agreement. See the section titled “*The Merger Agreement*” beginning on page 146 for a detailed discussion of the terms and conditions of the Merger Agreement. In particular, Diffusion’s board of directors considered the following:
 - o the calculation of the Exchange Ratio used to establish the number of shares of Diffusion Common Stock to be issued to EIP’s stockholders in the Merger, subject to adjustment in accordance with the Merger Agreement based on the amount of Diffusion’s net cash;
 - o the limited number and nature of the conditions to the parties’ obligations to consummate the transactions contemplated by the Merger Agreement and the Diffusion board of directors’ belief as to the likelihood of satisfying such conditions in light of the parties’ obligations to use commercially reasonable efforts to consummate and make effective the transactions contemplated by the Merger Agreement;
 - o the provisions in the Merger Agreement that provide for the ability of Diffusion’s board of directors to withdraw or modify its recommendation that holders of Diffusion Common Stock approve the issuance of shares of Diffusion Common Stock and the Reverse Split following the receipt of an alternative acquisition proposal that Diffusion’s board of directors determines in good faith (after consultation with its outside counsel and its financial advisor) is a superior proposal (as defined in the section titled “*The Merger Agreement*” beginning on page 146), subject to certain restrictions imposed by the Merger Agreement, including that Diffusion’s board of directors shall have determined in good faith (after consultation with its outside legal counsel) that the failure to take such action would be inconsistent with its fiduciary duties to Diffusion’s stockholders under applicable law and that EIP shall have been given an opportunity to match the superior proposal; and
 - o in response to an intervening event (as defined in the section titled “*The Merger Agreement*” beginning on page 146), subject to certain restrictions imposed by the Merger Agreement, including that Diffusion’s board of directors have determined in good faith (after consultation with its outside counsel) that the failure to take such action would be inconsistent with its fiduciary duties to Diffusion’s stockholders under applicable law and provided EIP with prior notice of its intention to take such action; and
 - that, in the view of Diffusion’s board of directors, the \$765,000 termination fee that could become payable by Diffusion pursuant to the Merger Agreement was reasonable, would likely not deter alternative acquisition proposals and would likely not be required to be paid unless Diffusion’s board of directors entered into an agreement providing for a transaction that would be more favorable to the Diffusion stockholders than the transactions contemplated by the Merger Agreement.
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- In the course of its deliberations, Diffusion board of directors also considered a variety of risks and other countervailing factors related to the Merger and other transactions contemplated by the Merger Agreement, including among others:
- the fact that Diffusion stockholders will be sharing participation of Diffusion’s upside with EIP stockholders as part of the combined company;
- the substantial expenses to be incurred in connection with the Merger and the other transactions contemplated by the Merger Agreement;
- the fact that projects of future results of operations and synergies are estimates based on assumptions that may not be realized within the expected time frame or at all;
- the possible volatility, at least in the short term, of the trading price of Diffusion Common Stock resulting from the announcement of the Merger Agreement;
- the risk that the Merger might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the Merger Agreement or on the delay or failure to complete the transactions contemplated by the Merger Agreement on Diffusion’s financial position;
- the terms of the Merger Agreement, including covenants relating to (1) the two companies’ conduct of their respective businesses during the period between the signing of the Merger Agreement and the completion of the Merger and the other transactions, including the requirement that the two companies’ conduct business only in the ordinary course, subject to specific exceptions and (2) the restrictions on Diffusion’s ability to solicit alternative transaction proposals;
- the fact that Diffusion may become obligated to pay EIP a termination fee of \$765,000 in certain circumstances as further discussed under the section titled “*The Merger Agreement*” beginning on page 146, which could potentially deter a potential acquirer from proposing an alternative transaction that may provide value to Diffusion stockholders superior to that of the proposed transactions;
- the potential for litigation relating to the proposed transactions and the associated costs, burden and inconvenience involved in defending those proceedings;
- the potential conflict of interest created by the fact that Diffusion’s executive officers and directors have financial or other interests in the Merger that may be different from, or in addition to, those of other stockholders, as more fully described below in “— *Interests of the Diffusion Directors and Executive Officers in the Merger*”; and
- various other risks associated with the combined company and the merger, including those described in the sections titled “*Risk Factors*” beginning on page 36 and “*Cautionary Statement Concerning Forward-Looking Statements*” beginning on page 100.

The foregoing information and factors considered by Diffusion’s board of directors are not intended to be exhaustive but are believed to include all of the material factors considered by Diffusion’s board of directors. In view of the wide variety of factors considered in connection with its evaluation of the Merger and the other transactions contemplated by the Merger Agreement and the complexity of these matters, Diffusion’s board of directors did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of Diffusion’s board of directors may have given different weight to different factors. Diffusion’s board of directors conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, Diffusion’s management team and legal and financial advisors, and considered the factors overall to be favorable to, and to support, its determination.

This explanation of the Diffusion board of directors’ reasons for approving the Merger Agreement and the transactions contemplated thereby and the other information presented in this section is forward-looking in nature and, therefore, should be read in light of the factors described in the section titled “*Cautionary Statement Concerning Forward-Looking Statements*” beginning on page 100.

EIP Reasons for the Merger

The following discussion sets forth material factors considered by EIP's board of directors in reaching its determination to approve the terms and authorize the execution of the Merger Agreement for the purpose of implementing the Merger; however, it may not include all of the factors considered by EIP's board of directors. In light of the number and wide variety of factors considered in connection with its evaluation of the Merger Agreement, EIP's board of directors did not consider it practicable to, and did not attempt to, quantify or otherwise assign relative weights to the specific factors it considered in reaching its determination. EIP's board of directors viewed its position and determinations as being based on all of the information available and the factors presented to and considered by it. In addition, individual directors may have given different weight to different factors.

In the course of reaching its decision to approve the terms and authorize the execution of the Merger Agreement for the purpose of consummating the Merger, EIP's board of directors consulted with EIP's senior management and legal counsel, reviewed a significant amount of information and considered a number of factors, including, among others:

- historical and current information concerning EIP's business, including its financial performance and condition, operations, management and competitive position;
- EIP's prospects if it were to remain an independent privately held company, including its need to obtain additional financing and the terms on which it would be able to obtain such financing, if at all;
- EIP's board of directors' belief that no alternatives to the Merger were reasonably likely to create greater value for EIP equity holders, after reviewing the various financing and other strategic options to enhance stockholder value that were considered by EIP's board of directors;
- the cash resources of the combined company expected to be available at the Effective Time and the anticipated burn rate of the combined organization;
- the broader range of investors to support the development of EIP's product candidates than it could otherwise obtain if it continued to operate as a privately held company;
- potential to provide its current stockholders with greater liquidity by owning stock in a public company;
- the expectation that the Merger with Diffusion would be a more time- and cost-effective means to access capital than other options considered;
- the expectation that substantially all of EIP's employees, particularly its management, will serve in similar roles at the combined organization;
- the fact that shares of Diffusion Common Stock issued to EIP equity holders will be registered on a Form S-4 registration statement and will become freely tradable for EIP equity holders who are not affiliates of EIP and who are not parties to the Lock-Up Agreements;
- the Support Agreements, pursuant to which certain directors and officers of Diffusion and certain directors, officers and stockholders of EIP have agreed, solely in their capacity as stockholders of Diffusion and EIP, respectively, to vote all of their shares of EIP capital stock or Diffusion Common Stock in favor of the adoption or approval, respectively, of the Merger Agreement;
- the ability to obtain a Nasdaq listing and comply with Nasdaq listing requirements;
- the terms and conditions of the Merger Agreement, including, without limitation, the following:
 - the expected relative percentage ownership of EIP equity holders and Diffusion securityholders in the combined company initially at the Effective Time and the implied valuation of EIP based on Diffusion's cash contribution to the combined company;
 - the parties' representations, warranties and covenants and the conditions to their respective obligations;
 - the limited number and nature of the conditions of the obligation of Diffusion to consummate the Merger; and
 - the likelihood that the Merger will be consummated on a timely basis.

- EIP’s Board also considered a number of uncertainties and risks in its deliberation concerning the Merger and the other transactions contemplated by the Merger Agreement, including the following:
- the risk that the potential benefits of the Merger Agreement may not be realized;
- the price volatility of Diffusion Common Stock, which may reduce the value of Diffusion Common Stock that EIP equity holders will receive at the Effective Time;
- the potential reduction in Diffusion’s net cash prior to the closing of the Merger;
- the possibility that under Diffusion could under certain circumstances consider unsolicited acquisition proposals if superior to the Merger;
- possibility that the Merger might not be completed for a variety of reasons, such as the failure of Diffusion to obtain the required stockholder vote, and the potential adverse effect on the reputation of EIP and the ability of EIP to obtain financing in the future in the event the Merger is not completed;
- risk that the Merger might not be consummated in a timely manner or at all;
- expenses to be incurred in connection with the Merger and related administrative challenges associated with combining the organizations;
- the additional expenses that EIP’s business will be subject to as a public company following the closing of the Merger to which it has not previously been subject;
- the potential conflict of interest created by the fact that EIP’s executive officers and directors have financial or other interests in the Merger that may be different from, or in addition to, those of other stockholders, as more fully described below in “— *Interests of the EIP Directors and Executive Officers in the Merger*”; and
- various other risks associated with the combined company and the merger, including those described in the sections titled “*Risk Factors*” beginning on page 36 and “*Cautionary Statement Concerning Forward-Looking Statements*” beginning on page 100. EIP’s board of directors weighed the benefits, advantages and opportunities of a potential transaction against the uncertainties and risks described above, as well as the possible diversion of management attention for an extended period of time. After taking into account these and other factors, EIP’s board of directors unanimously approved the terms and authorized execution of the Merger Agreement for the purpose of implementing the Merger.

Opinion of Diffusion’s Financial Advisor

CG is acting as exclusive financial advisor to Diffusion in connection with the Merger. At a meeting of the Diffusion board of directors held on March 29, 2023 to evaluate the Merger, CG delivered to the Diffusion board of directors an oral opinion, which opinion was confirmed by delivery of a written opinion, dated March 29, 2023, to the effect that, as of that date and based upon and subject to certain assumptions, factors and qualifications set forth in the written opinion, the Exchange Ratio pursuant to the Merger Agreement was fair, from a financial point of view, to Diffusion. For purposes of CG’s opinion and related analyses, “Exchange Ratio” means the ratio obtained by dividing the Company Merger Shares by the Company Outstanding Shares as described in the Merger Agreement, which as of immediately prior to the execution of the Merger Agreement was calculated to be 0.1860 based on the respective capitalization of Diffusion and EIP as provided by Diffusion and EIP management. For purposes of its opinion, and at the direction and with the consent of the Diffusion board of directors, CG assumed that the Parent Net Cash (as defined in the Merger Agreement) will not be less than \$13.5 million nor more than \$14.5 million, and the Parent Allocation Percentage (as defined in the Merger Agreement) will be 0.2275 without adjustment. CG did not express any view on, and its opinion did not address, any other term or aspect of any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with the Merger.

The full text of CG's written opinion is attached to this proxy statement/prospectus/information statement as Annex C and is incorporated into this proxy statement/prospectus/information statement by reference. The description of CG's opinion set forth in this proxy statement/prospectus/information statement is qualified in its entirety by reference to the full text of such opinion. Diffusion stockholders are encouraged to read CG's opinion carefully and in its entirety for a description of the procedures followed, assumptions made, matters considered and qualifications and limitations on the review undertaken by CG in connection with its opinion. CG's opinion was addressed to the Diffusion board of directors, was only one of many factors considered by the Diffusion board of directors in its evaluation of the Merger and only addresses the fairness, from a financial point of view and as of the date of the opinion, to Diffusion of the Exchange Ratio pursuant to the Merger Agreement. CG's opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to Diffusion, nor does it address the underlying business decision of Diffusion to proceed with the Merger or any view on any other term or aspect of the Merger. CG's opinion was solely directed to and for the information of the Diffusion board of directors (in its capacity as such) in connection with its evaluation of the Merger and does not constitute advice or a recommendation to the Diffusion board of directors, any stockholder of Diffusion or any other person as to how the Diffusion board of directors or such stockholder or other person should vote with respect to the Merger or otherwise act on any other matter relating to the Merger. CG's opinion was necessarily based on securities, economic, market and monetary conditions prevailing on, and the information made available to CG as of, March 28, 2023, the trading day immediately prior to delivery of its opinion. Subsequent developments may affect the conclusions expressed in CG's opinion if such opinion were rendered as of a later date, and CG disclaims any obligation to advise any person of any change in any manner affecting its opinion that may come to CG's attention after the date of its opinion. CG has assumed no responsibility for updating, revising or reaffirming its opinion based on circumstances or events occurring after the date of the opinion.

In connection with CG's review of the Merger and developing the opinion described above, CG, among other things:

- (i) reviewed certain publicly available information relating to Diffusion and EIP;
- (ii) reviewed certain internal historical financial statements and other historical financial and operating data concerning Diffusion and EIP provided to CG by management of Diffusion and EIP;
- (iii) reviewed certain projected cash balances of Diffusion prepared by management of Diffusion and certain projected financial and operating data of EIP prepared by management of EIP and adjusted by Diffusion, in each case as provided to CG by management of Diffusion (the "Projections");
- (iv) conducted discussions with members of senior management of Diffusion and EIP regarding the past and current operations and financial condition and the prospects of Diffusion and EIP;
- (v) reviewed certain financial and stock market data of certain publicly traded companies that CG deemed to be relevant to EIP;
- (vi) reviewed certain financial terms of certain initial public offerings executed by certain companies that CG deemed to be relevant to EIP;
- (vii) reviewed certain financial terms of certain business combination transactions that CG deemed to be relevant to the Merger;
- (viii) reviewed the terms of the Merger Agreement furnished to CG by Diffusion on March 28, 2023, which CG assumed, with the consent of the Diffusion board of directors, to be identical in all material respects to the agreement to be executed by the parties; and
- (ix) reviewed such other financial studies and analyses, performed such other investigations, and took into account such other matters as CG deemed necessary, including an assessment of general securities, economic, market and monetary conditions.

In connection with its review and arriving at its opinion, CG did not independently verify any of the foregoing information, relied on such information, assumed that all such information was complete and accurate in all material respects, and relied on assurances of the managements of Diffusion and EIP that they were not aware of any facts that would make such information misleading in any material respect. With respect to the Projections and other estimated or forward-looking information provided to CG by management of Diffusion or EIP, CG assumed, with the consent of the Diffusion board of directors, that such information was reasonably prepared on bases reflecting the best currently available estimates and judgments of such management. At the direction of the Diffusion board of directors, CG reviewed and relied on the Projections for purposes of its analysis and opinion. CG expressed no view or opinion as to the Projections or the assumptions on which they were based, including, but not limited to, any assumptions regarding access to funding for EIP over the projection period.

CG also assumed that (i) the Merger will be consummated upon the terms set forth in the Merger Agreement, without waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to CG's analysis, (ii) the representations and warranties made by the parties to the Merger Agreement were and will be true and correct in all respects material to CG's analysis, and (iii) in the course of obtaining necessary governmental, regulatory and third-party approvals and consents for the Merger, no modification, delay, limitation, restriction or conditions will be imposed that will have an adverse effect on Diffusion or EIP or the contemplated benefits of the Merger in any way meaningful to CG's analysis. CG is not a legal, accounting, regulatory or tax expert and relied on the assessments made by Diffusion and its advisors with respect to such matters.

CG's opinion is limited to and addresses only the fairness, from a financial point of view, to Diffusion of the Exchange Ratio pursuant to the Merger Agreement as of the date of the opinion. CG did not express any view on, and its opinion did not address, any other term or aspect of any other agreement or arrangements contemplated by the Merger Agreement or entered into in connection with the Merger, including, but not limited to, (i) any Parent Reverse Split, the Lock-Up Agreements, the Parent Stockholder Support Agreements, or the Company Stockholder Support Agreements (each as defined in the Merger Agreement), or (ii) any equity financing by Diffusion permitted under the Merger Agreement. CG expressed no opinion as to the fairness of the Merger to the holders of any class of securities, creditors or other constituencies of Diffusion or EIP. CG's opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to Diffusion, nor does it address the underlying business decision of Diffusion to proceed with the Merger or any view on any other term or aspect of the Merger Agreement. CG did not consider, and did not express an opinion as to, the fairness of the amount or nature of the compensation to be paid to any of the officers, directors or employees of Diffusion or EIP, or class of such persons. Further, CG did not express any view or opinion as to in the future what the value of Diffusion Common Stock actually will be when issued or the price or range of prices at which Diffusion Common Stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the Merger.

CG's opinion was rendered on the basis of securities, economic, market and monetary conditions prevailing as of March 28, 2023 (the trading day immediately prior to delivery of CG's opinion) and on the prospects, financial and otherwise, of Diffusion and EIP, known to CG as of such date. CG was not requested to conduct, and did not conduct, nor did CG rely upon, any independent valuation or appraisal of any of the assets or liabilities of Diffusion or EIP. CG also did not evaluate the solvency of any party to the Merger Agreement under any state, federal or other laws, rules or regulations relating to bankruptcy, insolvency or similar matters. In addition, with the consent of the Diffusion board of directors, CG assumed that any material liabilities (contingent or otherwise, known or unknown) of Diffusion or EIP are as set forth in the financial statements of Diffusion or EIP provided to CG.

Summary of Financial Analyses

The following is a summary of the material financial analyses performed by CG in connection with rendering its opinion dated March 29, 2023 described above. The following summary, however, does not purport to be a complete description of the factors considered or financial analyses performed by CG, nor does the order of analyses described represent relative importance or weight given to those analyses by CG. Some of these summaries of the financial analyses include information presented in tabular format. The tables must be read together with the full text of each summary and are alone not a complete description of CG's financial analyses. In performing its analyses, CG made numerous assumptions with respect to industry performance, general business and economic conditions and other matters, many of which are beyond the control of Diffusion, EIP or any other parties to the Merger Agreement. Any estimates contained in these analyses are not necessarily indicative of actual values or predictive of future results or values, which may be significantly more or less favorable than as set forth below. Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before March 28, 2023 (the trading day immediately prior to delivery of CG's opinion) and is not necessarily indicative of current market conditions.

Diffusion

Diffusion Trading Analysis. CG considered the trading value of Diffusion as of March 28, 2023, the last trading day prior to the delivery of its opinion. For this purpose, CG calculated Diffusion's implied equity value based on its fully diluted shares outstanding (using the treasury stock method to determine additional dilution from outstanding restricted stock units, but excluding out-of-the money stock options and warrants) as provided by Diffusion management, *multiplied* by the closing price of the Diffusion Common Stock of \$4.86 per share on such date. Based on this analysis, CG noted that, as of March 28, 2023, the implied equity value of Diffusion was approximately \$9.9 million and the implied total enterprise value of Diffusion was approximately (\$4.3) million (calculated as equity value, *plus* estimated debt as of closing of \$0, *minus* estimated cash and cash equivalents as of closing of \$14.2 million, in each case based on information provided by Diffusion management).

Diffusion Liquidation Analysis. CG considered a liquidation analysis, consisting of projected cash balances for Diffusion prepared by Diffusion management, in connection with the rendering of its opinion, in assessing the value, if any, that holders of shares of Diffusion Common Stock would be expected to receive in respect of such shares in the event that Diffusion were liquidated. The liquidation proceeds were estimated by Diffusion management assuming no asset sales and an estimated completion date for the liquidation of May 31, 2023. Based on this analysis provided by Diffusion management, CG noted that management estimated that, as of May 31, 2023, there would be approximately \$12.6 million of cash available for distribution to holders of Diffusion Common Stock, or approximately \$6.19 per fully diluted share outstanding (using the treasury stock method to determine additional dilution from outstanding restricted stock units, but excluding out-of-the money stock options and warrants) as provided by Diffusion management.

Diffusion Selected Reverse Mergers Analysis. CG reviewed publicly available financial information related to selected U.S. publicly traded biopharmaceutical companies that CG, based on its experience and professional judgment, deemed relevant to consider in relation to Diffusion and the Merger. Each of such selected companies pursued a reverse merger that was completed or announced between January 1, 2019 and March 28, 2023, where the publicly traded company had between \$10.0 million and \$20.0 million of expected or announced cash as of the closing of the merger. No company utilized in the selected reverse mergers analysis is directly comparable to Diffusion and certain of these companies may have financial, business and/or operating characteristics that are materially different from those of Diffusion. Moreover, none of the reverse mergers pursued by the selected companies is directly comparable to the Merger. However, the companies were selected, among other reasons, because they have businesses and cash positions that, for purposes of CG's analysis, may be considered similar to that of Diffusion.

The selected public companies and reverse mergers are listed below (company names are as of the announcement date):

<u>Announcement Date</u>	<u>Public Company</u>	<u>Private Company</u>
2/23/23	Vascular Biogenics Ltd.	Notable Labs, Inc.
3/15/21	Intec Pharma Ltd.	Decoy Biosystems, Inc.
11/30/20	Sunesis Pharmaceuticals, Inc.	Viracta Therapeutics, Inc.
7/29/20	Spring Bank Pharmaceuticals, Inc.	F-Star Therapeutics Limited
7/6/20	Unum Therapeutics Inc.	KIQ LLC
1/28/20	Conatus Pharmaceuticals Inc.	Histogen Inc.
3/7/19	GTx, Inc.	Oncternal Therapeutics, Inc.

CG calculated the implied total enterprise value of each of the public companies in the selected reverse mergers based on information obtained from filings with the SEC, Bloomberg, the S&P Capital IQ database, and other public sources. For this analysis, CG calculated total enterprise value as pre-announcement, fully diluted equity value (using the treasury stock method to determine additional dilution from in-the-money stock options and warrants), *plus* pre-announcement total debt (excluding accrued liabilities, accounts payable and/or warrant liabilities, and including minority interest and preferred stock, in each case as applicable), *minus* pre-announcement cash and cash equivalents such as marketable securities and short-term investments. Based on its analysis and other considerations that CG deemed relevant in its experience and professional judgment, CG derived a range of implied total enterprise values for Diffusion based on the first quartile and third quartile enterprise values of the public companies in the selected reverse mergers of (\$15.8) million and \$2.6 million, respectively. Applying this range of implied total enterprise values and adding to such range Diffusion's estimated cash and cash equivalents as of closing of \$14.2 million and subtracting Diffusion's estimated total debt as of closing of \$0 (in each case based on information provided by Diffusion management), CG derived a range of implied equity values for Diffusion of (\$1.6) million to \$16.8 million. CG then derived a range of implied per share equity values for Diffusion of not meaningful (NM) to \$8.23 based on the fully diluted shares outstanding of Diffusion Common Stock (using the treasury stock method to determine additional dilution from outstanding restricted stock units, but excluding out-of-the money stock options and warrants) as provided by Diffusion management.

EIP

EIP Selected Public Companies Analysis. CG reviewed certain publicly available financial information for clinical-stage neurodegenerative companies that, based on its experience and professional judgment, share similar business characteristics to EIP. No company utilized in the selected public companies analysis is directly comparable to EIP and certain of these companies may have financial, business and/or operating characteristics that are materially different from those of EIP. However, the companies were selected, among other reasons, because they are publicly traded companies with businesses that, for purposes of CG's analysis, may be considered similar to that of EIP based on industry sector and stage of development of key products. The selected public companies are listed below:

BioVie Inc.
Vigil Neuroscience, Inc.
Wave Life Sciences Ltd.
Annovis Bio, Inc.
Clene Inc.
iNmune Bio Inc.
Larimar Therapeutics, Inc.
AC Immune SA
Alzamend Neuro, Inc.
Cognition Therapeutics, Inc.

CG calculated the implied total enterprise value of each of the public companies based on information obtained from filings with the SEC, the S&P Capital IQ database, and other public sources. For this analysis, CG calculated total enterprise value as fully diluted equity value (using the treasury stock method and adjusted for financings), *plus* total debt (adjusted for debt financings, as applicable), *minus* cash and cash equivalents (adjusted for financings and milestone payments, as applicable). Total enterprise value also included additions from minority interests, as applicable. Based on its analysis and other considerations that CG deemed relevant in its experience and professional judgment, CG derived a range of implied total enterprise values for EIP based on the first quartile and third quartile enterprise values of the selected public companies of \$65.0 million and \$144.1 million, respectively. Applying this range of implied total enterprise values and adding to such range EIP's estimated cash and cash equivalents as of closing of \$2.0 million and subtracting EIP's estimated total debt as of closing of \$0 assuming EIP's convertible debt converts into equity as provided in the Merger Agreement (in each case based on information provided by EIP management), CG derived a range of implied equity values for EIP of \$67.0 million to \$146.1 million. CG then derived a range of implied per share equity values for EIP of \$1.80 to \$3.92 based on the fully diluted shares outstanding of EIP Common Stock (using the treasury stock method to determine additional dilution from the conversion of outstanding preferred stock and convertible notes and in-the-money equity awards, but excluding out-of-the money stock options and warrants) as provided by EIP management.

EIP Selected Initial Public Offering Precedent Analysis. CG reviewed certain publicly available financial information related to initial public offerings (IPOs) of selected clinical-stage neurodegenerative companies since January 2018 that, based on CG's experience and professional judgment, share similar business characteristics to EIP. No company utilized in the selected precedent IPO analysis is directly comparable to EIP and certain of these companies may have financial, business and/or operating characteristics that are materially different from those of EIP. However, the companies were selected, among other reasons, because they are recent issuers in IPOs with businesses that, for purposes of CG's analysis, may be considered similar to that of EIP based on industry sector and the stage of development of key products.

The selected IPOs are listed below:

<u>IPO Pricing Date</u>	<u>Issuer</u>
1/6/22	Vigil Neuroscience, Inc.
12/8/21	NeuroSense Therapeutics Ltd.
10/7/21	Cognition Therapeutics, Inc.
12/22/20	Inhibikase Therapeutics, Inc.
9/17/20	Athira Pharma, Inc.
1/28/20	Annovis Bio, Inc.
5/8/19	Cortexyme, Inc.
8/9/18	Vaccinex, Inc.

CG calculated the pre-money implied total enterprise value of the issuer in each of the IPOs at the time of pricing of such IPO based on information obtained from filings with the SEC, the S&P Capital IQ database, and other public sources. For this analysis, CG calculated total enterprise value as fully diluted, post-money equity value based on the IPO offer price *minus* the capital raised in the IPO (excluding any overallotment option and adjusted for offering expenses), *plus* debt and preferred stock not converted in the IPO, *minus* cash and cash equivalents as of the latest filing of the issuer (adjusted for financing events between the date of the latest financial statements and the IPO). Based on its analysis and other considerations that CG deemed relevant in its experience and professional judgment, CG derived a range of implied total enterprise values for EIP based on the first quartile and third quartile total enterprise values of the issuers in the selected IPOs of \$88.7 million and \$260.8 million, respectively. Applying this range of implied total enterprise values and adding to such range EIP's estimated cash and cash equivalents as of closing of \$2.0 million and subtracting EIP's estimated total debt as of closing of \$0 assuming EIP's convertible debt converts into equity as provided in the Merger Agreement (in each case based on information provided by EIP management), CG derived a range of implied equity values for EIP of \$90.7 million to \$262.8 million. CG then derived a range of implied per share equity values for EIP of \$2.43 to \$7.05 based on the fully diluted shares outstanding of EIP Common Stock (using the treasury stock method to determine additional dilution from the conversion of outstanding preferred stock and convertible notes and in-the-money equity awards, but excluding out-of-the money stock options and warrants) as provided by EIP management.

EIP Discounted Cash Flow Analysis. CG conducted a discounted cash flow analysis for EIP for the purpose of calculating a range of equity values per share of EIP Common Stock on a stand-alone basis. A discounted cash flow analysis is a traditional valuation methodology used to derive a valuation of an asset or set of assets by calculating the "present value" of estimated future cash flows of the asset or set of assets. "Present value" refers to the current value of future cash flows or amounts and is obtained by discounting those future cash flows or amounts by a discount rate that takes into account macroeconomic assumptions and estimates of risk, the opportunity cost of capital, expected returns and other appropriate factors. For purposes of this analysis, CG was directed by the Diffusion board of directors to utilize financial projections provided by EIP management as adjusted by Diffusion management (see the section titled "*The Merger — Certain Unaudited Long-Range Financial Projections of EIP's Business*" below) to determine estimated unlevered free cash flows for EIP for calendar years 2023 through 2036. For this purpose, estimated unlevered free cash flows were calculated by taking net operating profit after taxes (NOPAT), adding depreciation, subtracting capital expenditures, and adjusting for changes in working capital.

CG calculated the net present value of such estimated unlevered free cash flows for EIP for calendar years 2023 through 2036. These values were discounted to net present values as of March 31, 2023 at a discount rate ranging from 14.0% to 18.0%, which range of discount rates was selected, upon the application of CG's professional judgment, based on an analysis of the weighted average cost of capital of the publicly traded companies referenced above in the section captioned "*-EIP Selected Public Companies Analysis*". Based on this analysis, CG derived a range of implied total enterprise values for EIP of \$283.3 million to \$399.0 million. CG then added to such range of implied total enterprise values EIP's estimated cash and cash equivalents as of closing of \$2.0 million and subtracted EIP's estimated total debt as of closing of \$0 assuming EIP's convertible debt converts into equity as provided in the Merger Agreement (in each case based on information provided by EIP management) to determine a range of implied equity values for EIP of \$285.3 million to \$401.0 million. Based on the outstanding shares of EIP Common Stock on a fully diluted basis (using the treasury stock method to determine additional dilution from the conversion of outstanding preferred stock and convertible notes and in-the-money equity awards, but excluding out-of-the money stock options and warrants) as provided by EIP management, CG then derived a range of implied per share equity values for EIP of \$7.66 to \$10.76.

Implied Pro Forma Ownership Percentage

Based on the analyses described above, CG considered the implied equity values for Diffusion derived from the Diffusion Trading Analysis, Diffusion Liquidation Analysis and Diffusion Selected Reverse Mergers Analysis (which ranged from \$9.9 million to \$16.8 million, excluding the first quartile result from the Diffusion Selected Reverse Mergers Analysis which was negative) with the range of implied equity values for EIP derived from the EIP Selected Public Companies Analysis (which ranged from \$67.0 million to \$146.1 million) to determine a range of implied pro forma percentage ownership for Diffusion equity holders in the combined company of 6.4% to 20.0%. CG compared this range to the 22.75% pro forma ownership percentage for Diffusion equity holders implied by the Parent Allocation Percentage as set forth in the Merger Agreement (without adjustment for Parent Net Cash).

CG also considered the implied equity values for Diffusion derived from the Diffusion Trading Analysis, Diffusion Liquidation Analysis and Diffusion Selected Reverse Mergers Analysis (which ranged from \$9.9 million to \$16.8 million, excluding the first quartile result from the Diffusion Selected Reverse Mergers Analysis which was negative) with the range of implied equity values for EIP derived from the EIP Selected Initial Public Offering Precedent Analysis (which ranged from \$90.7 million to \$262.8 million) to determine a range of implied pro forma percentage ownership for Diffusion equity holders in the combined company of 3.6% to 15.6%. CG compared this range to the 22.75% pro forma ownership percentage for Diffusion equity holders implied by the Parent Allocation Percentage as set forth in the Merger Agreement (without adjustment for Parent Net Cash).

Finally, CG considered the implied equity values for Diffusion derived from the Diffusion Trading Analysis, Diffusion Liquidation Analysis and Diffusion Selected Reverse Mergers Analysis (which ranged from \$9.9 million to \$16.8 million, excluding the first quartile result from the Diffusion Selected Reverse Mergers Analysis which was negative) with the range of implied equity values for EIP derived from the EIP Discounted Cash Flow Analysis (which ranged from \$285.3 million to \$401.0 million) to determine a range of implied pro forma percentage ownership for Diffusion equity holders in the combined company of 2.4% to 5.6%. CG compared this range to the 22.75% pro forma ownership percentage for Diffusion equity holders implied by the Parent Allocation Percentage as set forth in the Merger Agreement (without adjustment for Parent Net Cash).

Implied Exchange Ratio

Based on the analyses described above, CG compared the implied per share equity values for Diffusion derived from the Diffusion Trading Analysis, Diffusion Liquidation Analysis and Diffusion Selected Reverse Mergers Analysis (which ranged from \$4.86 to \$8.23 per share, excluding the first quartile result from the Diffusion Selected Reverse Mergers Analysis which was NM) with the range of implied per share equity values for EIP derived from the EIP Selected Public Companies Analysis of \$1.80 to \$3.92 to determine a range of implied exchange ratios for the issuance of Diffusion Common Stock to EIP equity holders in the Merger of 0.807x to 0.219x. CG compared this range to the Exchange Ratio of 0.1860 calculated as set forth in the Merger Agreement (without adjustment for Parent Net Cash).

CG also compared the implied per share equity values for Diffusion derived from the Diffusion Trading Analysis, Diffusion Liquidation Analysis and Diffusion Selected Reverse Mergers Analysis (which ranged from \$4.86 to \$8.23 per share, excluding the first quartile result from the Diffusion Selected Reverse Mergers Analysis which was NM) with the range of implied per share equity values for EIP derived from the EIP Selected IPO Precedent Analysis of \$2.43 to \$7.05 to determine a range of implied exchange ratios for the issuance of Diffusion Common Stock to EIP equity holders in the Merger of 1.451x to 0.296x. CG compared this range to the Exchange Ratio of 0.1860 calculated as set forth in the Merger Agreement (without adjustment for Parent Net Cash).

Finally, CG compared the implied per share equity values for Diffusion derived from the Diffusion Trading Analysis, Diffusion Liquidation Analysis and Diffusion Selected Reverse Mergers Analysis (which ranged from \$4.86 to \$8.23 per share, excluding the first quartile result from the Diffusion Selected Reverse Mergers Analysis which was NM) with the range of implied per share equity values for EIP derived from the EIP Discounted Cash Flow Analysis of \$7.66 to \$10.76 to determine a range of implied exchange ratios for the issuance of Diffusion Common Stock to EIP equity holders in the Merger of 2.214x to 0.931x. CG compared this range to the Exchange Ratio of 0.1860 calculated as set forth in the Merger Agreement (without adjustment for Parent Net Cash).

General

The preparation of a fairness opinion is a complex process and is not necessarily susceptible to partial analysis or summary description. Selecting portions of the analyses or of the summary set forth above, without considering the analyses as a whole, could create an incomplete view of the processes underlying CG's opinion. In arriving at its fairness determination, CG considered the results of all of its analyses and did not attribute any particular weight to any factor or analysis considered by it. Rather, CG made its determination as to fairness on the basis of its experience and professional judgment after considering the results of all of its analyses, taken as a whole. No company or transaction used in the above analyses as a comparison is directly comparable to Diffusion, EIP or the Merger. The reasons for and the circumstances surrounding each of the selected companies and transactions analyzed were diverse and there are inherent differences in the business, operations, financial condition and prospects of EIP or Diffusion, as applicable, and the companies included in those analyses.

CG prepared these analyses for purposes of providing its opinion to the Diffusion board of directors as to the fairness, from a financial point of view and as of the date of the opinion, to Diffusion of the Exchange Ratio pursuant to the Merger Agreement. These analyses do not purport to be appraisals, nor do they necessarily reflect the prices at which businesses or securities actually may be sold.

The Exchange Ratio was determined through negotiations between Diffusion and EIP and was approved by the Diffusion board of directors. CG provided advice to the Diffusion board of directors during these negotiations. CG, however, did not recommend any specific amount of consideration to Diffusion or the Diffusion board of directors or that any specific amount of consideration constituted the only appropriate consideration for the Merger.

As described above, CG's opinion to the Diffusion board of directors was one of many factors taken into consideration by the Diffusion board of directors in making its determination to approve the Merger Agreement. The foregoing summary does not purport to be a complete description of the factors considered or financial analyses performed by CG in connection with its opinion and is qualified in its entirety by reference to the full text of the written opinion of CG attached to this proxy statement/prospectus/information statement as *Annex C*. The issuance of CG's opinion was approved by a fairness committee of CG.

CG, as part of its investment banking activities, is regularly engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, secondary distributions of listed and unlisted securities, private placements and valuations for corporate and other purposes. In the ordinary course of business, CG and its affiliates may acquire, hold or sell, for its and its affiliates' own accounts and the accounts of customers, equity, debt and other securities and financial instruments (including bank loans and other obligations) of Diffusion and EIP, certain of their respective affiliates and any other company that may be involved in the Merger. In the two years prior to the date of its opinion, CG had not provided investment banking or other financial services of a material nature to either Diffusion or EIP, except in connection with its current engagement by Diffusion related to the Merger. CG may provide investment banking and other services to or with respect to Diffusion, EIP or their respective affiliates in the future for which CG may receive compensation.

Diffusion engaged CG as its financial advisor because it is a nationally recognized investment banking firm that has substantial experience in transactions similar to the Merger. Pursuant to the terms of such engagement, Diffusion agreed to pay CG fees for its services in connection with the Merger in an aggregate amount of \$2.0 million as follows: (i) \$50,000 payable upon signing of the engagement letter; (ii) \$25,000 payable each quarter during the term of CG's engagement; (iii) \$500,000 payable upon delivery by CG of its opinion dated March 29, 2023; and (iv) the remainder contingent upon consummation of the Merger. In addition, Diffusion has agreed to reimburse CG for certain expenses and to indemnify CG and related persons for certain liabilities relating to or arising out of its engagement.

Certain Unaudited Long-Range Financial Projections of EIP's Business

As a matter of course, neither Diffusion nor EIP publicly discloses forecasts or long-term projections as to future performance, revenues, earnings or other results of operations due to the inherent unpredictability and subjectivity of the underlying assumptions and estimates. However, in connection with Diffusion's evaluation of the proposed transaction, EIP's management prepared preliminary internal financial projections with respect to EIP's business. Following revisions during the due diligence process by and at the direction of EIP management to reflect the passage of time and feedback from Diffusion management, these projections were then adjusted by Diffusion management in the manner described below (such adjusted projections, the "Financial Projections" or the "Projections"), for consideration by the Diffusion board of directors in evaluating the Merger and for use by CG at the direction of the Diffusion board of directors in connection with the rendering of its fairness opinion to the Diffusion board of directors and performing its related financial analyses, as further described above under the heading, "*The Merger—Opinion of Diffusion's Financial Advisor.*" A summary of the Financial Projections, which constitute all material financial projections reviewed and considered by Diffusion's board of directors in reaching its recommendations relating to the Merger and the related transactions, is set forth below.

The Financial Projections are not included or intended to influence any stockholder's views on the Merger and are summarized in this proxy statement/prospectus solely to provide stockholders access to certain non-public information regarding EIP's business considered by the Diffusion board of directors as part of CG's fairness opinion and related financial analyses. The Financial Projections do not take into account any events or circumstances after the date they were prepared, including the announcement of the Merger and are, by their nature, subjective, uncertain, and susceptible to multiple interpretations and periodic revisions based on actual experience and business developments. Although Diffusion and EIP believe their respective assumptions to be reasonable, due to the inherent uncertainty of financial projections, Diffusion and EIP expect that differences will exist between actual and projected results and that those differences could be material. Although presented with numerical specificity, the Financial Projections reflect numerous variables, estimates and assumptions made by EIP and Diffusion management at the time the underlying information and projections were prepared, including assumptions regarding the ability to obtain regulatory approvals, the expected timing of such approvals, general business, economic, market and financial conditions, and other matters, all of which are difficult to predict and many of which are beyond the control of any party. The information from the Financial Projections should be evaluated, if at all, in conjunction with the historical financial statements and other information regarding EIP in this proxy statement/prospectus/information statement, and there can be no assurance that the estimates and assumptions made in preparing the Financial Projections will prove accurate, that any of the Financial Projections will be realized, or that, if the Merger is completed, the combined company's future financial results will not materially vary from the Financial Projections. The Financial Projections may also differ materially from published analyst estimates and forecasts.

Accordingly, the inclusion of the Financial Projections and the other information about such projections in this proxy statement/prospectus/information statement should not be regarded as an indication that Diffusion, CG, EIP or any other recipient of this information considered, or now considers, this information to be predictive of actual future results, nor should it be deemed an admission or representation by Diffusion, CG, EIP or any of their respective officers, directors, affiliates, advisors or other representatives with respect to such projections. In particular, the Financial Projections should not be utilized as public guidance. Furthermore, neither the independent registered public accounting firm of Diffusion nor EIP, nor any other independent accountant, has audited, reviewed, compiled, examined or performed any procedures with respect to the Financial Projections for the purpose of its inclusion herein, and accordingly, no independent accountant is expressing any opinion or providing any form of assurance with respect thereto for the purpose of this proxy statement/prospectus. Without limitation of the foregoing, the KPMG LLP reports included in this proxy statement/prospectus/information statement relate to the previously issued financial statements of Diffusion, do not extend to the Financial Projections, and should not be read to do so.

Notwithstanding the foregoing, Diffusion's management and Diffusion's board of directors believed that, while only forming a part of the analysis involved with the approval of the Merger and the related transactions and the board of directors' recommendation of approval to Diffusion's stockholders, it was nonetheless helpful to the board of directors' process and determinations to review the Financial Projections given that EIP is a clinical stage company and the performance of the combined company following the closing of the Merger would be contingent upon, in part, the market opportunity for EIP.

The Financial Projections were prepared for internal use and were not prepared with a view toward public disclosure or compliance with published guidelines of the SEC regarding projections and GAAP. The Financial Projections include total adjusted revenue, earnings before interest and tax (EBIT) and unlevered free cash flow. Such non-GAAP measures as used herein may not be directly comparable to similarly titled measures used by other companies and should not be considered in isolation from, or as a substitute for, financial information presented in accordance with GAAP. Reconciliations of the non-GAAP financial measures in the Financial Projections to GAAP financial measures were not provided to or considered by Diffusion's board of directors or CG and Diffusion has not provided a reconciliation of the financial measures included in the Financial Projections to the relevant GAAP financial measures in this proxy statement/prospectus. SEC rules which otherwise would require a reconciliation of a non-GAAP financial measure to a GAAP financial measure for purposes of public disclosure do not apply to non-GAAP financial measures provided to a board of directors or financial advisors in connection with a proposed business combination transaction such as the Merger, if the disclosure is included in a document such as this proxy statement/prospectus/information statement to comply with requirements under state laws, including case law. The Financial Projections were provided by Diffusion to CG in connection with CG's performance of its financial analyses and delivery of its opinion to Diffusion's board of directors in connection with its consideration of the Merger and related transactions and, in order to provide a fair summary of the foregoing, Diffusion believes it may have an obligation to disclose such projections under applicable Delaware law.

The Financial Projections are based on numerous variables, estimates, and assumptions relating to the business, earnings, expenses, cash flows, assets, liabilities and prospects of the combined company, industry metrics, the likelihood and timing of regulatory approvals and, if approved, the degree of commercial success for EIP's product candidates. As noted above, in connection with Diffusion's evaluation of the proposed transaction, EIP's management prepared preliminary internal financial projections with respect to EIP's business for review by Diffusion and CG as part of Diffusion's due diligence activities related to the transaction. These initial projections were prepared in good faith by EIP's management based on management's reasonable best estimates and facts, circumstances and information available at the time. However, following its review of the initial projections and preliminary discussions with CG regarding the estimates and assumptions used therein, Diffusion management determined that a revised set of projections adjusting certain underlying assumptions would be more appropriate. As further described below, Diffusion management believed the revised assumptions utilized in the Financial Projections to be reasonable and appropriate based on, among other things, its due diligence of EIP, its experience and knowledge of the pharmaceutical industry and drug development process, and its desire to present a more conservative case for EIP's future business prospects for the Diffusion board of directors to consider in connection with evaluating the Merger due to the inherent uncertainty of financial projections described above.

The material differences between the assumptions used in the financial projections prepared by EIP and the projections as adjusted by Diffusion management based upon their collective experience and used in the Financial Projections are as follows:

- The financial projections provided to Diffusion management by EIP included revenues derived from and expenses exclusively related to the development of neflamapimod as a treatment for multiple indications, including DLB, early-onset Alzheimer's Disease and recovery after anterior circulation ischemic stroke. After evaluation of the model, Diffusion management limited the Financial Projections to include only those revenues derived from and expenses related only to neflamapimod's development as a treatment for DLB.
- The financial projections prepared by EIP included revenues derived from and expenses exclusively related to the future sale and marketing of neflamapimod in territories outside of the U.S. The Financial Projections were revised to include only those revenues derived from and expenses related to the future sale and marketing neflamapimod in the U.S.
- The Financial Projections adjusted the calculation of costs of goods sold in future periods to align with the corresponding assumptions underlying the calculation of revenue for such periods.

- The Financial Projections include increased working capital balances in future periods to better reflect the working capital requirements of a revenue-stage company in the pharmaceutical/biotechnology industry.
- The Financial Projections include increased general and administrative costs in all periods to better reflect the general and administrative expenses of a public company in the pharmaceutical/biotechnology industry.

Except as described above regarding the revised assumptions used therein, the Financial Projections were prepared by, and are the responsibility of, EIP’s management. The Financial Projections included above are not being included herein to influence Diffusion’s stockholders’ decision whether to vote in favor of any proposal contained in this proxy statement/prospectus/information statement and Diffusion stockholders are urged to review the section titled “Risk Factors” of this proxy statement/prospectus/information statement for a further description of the risks relating to the Merger, EIP’s business and Diffusion’s business. In particular, for a further description of risks related to the Financial Projections, see “Risks Related to the Merger — The financial projections for EIP included in the section titled “The Merger — Opinion of Diffusion’s Financial Advisor” which were considered by the Diffusion board of directors in evaluating the Merger and used by CG at the direction of the Diffusion board of directors in connection with its fairness opinion and related financial analyses, reflect numerous variables, estimates and assumptions and are inherently uncertain. If any of these variables, estimates and assumptions prove to be wrong, such as the assumptions relating to the approval of EIP’s product candidates, the actual results for the combined company’s business may be materially different from the results reflected in the financial projections.” Diffusion stockholders are also urged to review Diffusion’s most recent SEC filings. Diffusion stockholders should also read the section titled “Cautionary Statement Concerning Forward-Looking Statements” of this proxy statement/prospectus/information statement for additional information regarding the risks inherent in forward-looking information such as the Financial Projections.

In light of the foregoing factors and the uncertainties inherent in financial projections, stockholders are cautioned not to place undue reliance, if any, on the Financial Projections.

Financial Projections

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036
Total Revenue (DLB US)	\$ -	\$ -	\$ -	\$ -	\$ 193.2	\$ 750.6	\$ 1,623.5	\$ 2,492.5	\$ 3,129.4	\$ 3,366.0	\$ 3,353.4	\$ 3,480.1	\$ 3,684.4	\$ 1,894.8
EBIT	\$ (8.7)	\$ (8.6)	\$ (62.1)	\$ (71.7)	\$ 33.6	\$ 505.1	\$ 1,018.3	\$ 1,623.9	\$ 2,031.1	\$ 2,179.0	\$ 2,167.4	\$ 2,248.6	\$ 2,380.2	\$ 1,238.9
Free Cash Flow	\$ (8.7)	\$ (8.6)	\$ (62.1)	\$ (71.7)	\$ 8.5	\$ 360.5	\$ 686.6	\$ 1,157.1	\$ 1,499.7	\$ 1,661.0	\$ 1,681.1	\$ 1,727.8	\$ 1,820.8	\$ 1,169.2

* All amounts in millions.

Interests of the Diffusion Directors and Executive Officers in the Merger

In considering the recommendation of Diffusion’s board of directors with respect to the issuance of shares of Diffusion Common Stock as contemplated by the Merger Agreement and the other matters to be acted upon by the Diffusion stockholders at the Diffusion special meeting, the Diffusion stockholders should be aware that certain members of the board of directors and executive officers of Diffusion have interests in the Merger that may be different from, or in addition to, the interests of the Diffusion stockholders. These interests relate to or arise from the matters described below. Diffusion’s board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the Merger Agreement and the transactions contemplated thereby, and to recommend that the Diffusion stockholders approve the Diffusion proposals to be presented to the Diffusion stockholders for consideration at the Diffusion special meeting as contemplated by this proxy statement/prospectus/information statement.

Continued Service

Certain of Diffusion’s existing directors are expected to remain directors of the combined company. Jane Hollingsworth, JD and Dr. Robert J. Cobuzzi, Jr. are expected to continue as directors of the combined company. Dr. Cobuzzi, Diffusion’s current President and Chief Executive Officer, is expected to continue as Chief Operating Officer of the combined company, and William Elder, Diffusion’s current General Counsel and Corporate Secretary, is expected to continue as General Counsel and Corporate Secretary of the combined company.

None of Ms. Hollingsworth, Dr. Cobuzzi or Mr. Elder will receive any change of control payments, transaction completion bonuses or other additional compensation if the Merger is completed.

See section titled “*Management Following the Merger — Executive Officers and Directors of the Combined Company Following the Merger*” beginning on page 247.

Stock Ownership and Support Agreements

As of May 5, 2023, Diffusion directors and executive officers held 4,458 outstanding shares of Diffusion Common Stock in the aggregate, vested Diffusion stock options covering 49,019 shares of Diffusion Common Stock and 1,343 Diffusion restricted stock awards. Diffusion’s current directors and executive officers who collectively own or control an aggregate of less than 0.2% of the outstanding shares of Diffusion Common Stock have entered into support agreements in connection with the Merger. For a more detailed discussion of the support agreements see the section titled “*Agreements Related to the Merger — Support Agreements and Written Consent*” beginning on page 166.

Indemnification and Insurance

As described in this proxy statement/prospectus/information statement, including in “— *Limitations of Liability and Indemnification*” below, Diffusion’s directors and officers will be entitled to certain ongoing rights of indemnification and coverage under directors’ and officers’ liability insurance policies.

Severance Payments

The Merger will not constitute a change of control event that would otherwise trigger payment of severance or potential acceleration of equity awards to any of Diffusion’s named executive officers in connection with the closing of the Merger.

Interests of the EIP Directors and Executive Officers in the Merger

In considering the recommendation of EIP’s board of directors with respect to approving the Merger, EIP stockholders should be aware that certain members of EIP’s board of directors and executive officers of EIP have interests in the Merger that may be different from, or in addition to, interests they have as EIP stockholders. Certain of EIP’s executive officers and directors have options, subject to vesting, to purchase shares of EIP capital stock that will be converted into and become options to purchase shares of Diffusion Common Stock. Certain of EIP’s directors and executive officers are expected to become directors and executive officers of the combined company at the Effective Time, and all of EIP’s directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement.

Ownership Interests

Certain of EIP's directors and executive officers currently hold shares of EIP capital stock. The table below sets forth the anticipated ownership of EIP capital stock by EIP's directors and executive officers immediately prior to the Effective Time based on their ownership of EIP's capital stock as of April 1, 2023.

Director or Executive Officer	Number of Shares of EIP Capital Stock Held Immediately Prior to closing of Merger
John Alam, M.D. (1)	12,893,827
Sylvie Grégoire, Pharm.D. (2)	12,893,827
Jeff Poulton (3)	142,872
Marwan Sabbagh, M.D.	-
Frank Zavrl (4)	2,416,852
Kelly Blackburn, MHA (5)	118,803
William Tanner, Ph.D.	-

- 1) Consists of (i) 50,000 shares of EIP Common Stock, (ii) 365,670 shares of EIP Common Stock issuable upon the conversion of EIP Convertible Notes, (iii) 6,031,244 shares of common stock underlying shares of Series A-1 preferred stock held by Dr. Alam; and (x) 50,000 shares of EIP Common Stock, (y) 365,670 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (z) 6,031,243 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock held by Dr. Grégoire, who is married to Dr. Alam. Dr. Alam disclaims beneficial ownership of the shares except to the extent of his indirect pecuniary interest therein.
- 2) Consists of (i) 50,000 shares of EIP Common Stock, (ii) 365,670 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (iii) 6,031,243 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock held by Dr. Grégoire; and (i) 50,000 shares of EIP Common Stock, (ii) 365,670 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (iii) 6,031,244 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock held by Dr. Alam, who is married to Dr. Grégoire. Dr. Grégoire disclaims beneficial ownership of the shares except to the extent of her indirect pecuniary interest therein.
- 3) Consists of (i) 69,738 shares of EIP Common Stock underlying shares of EIP's Series A-2 preferred stock and (ii) 73,134 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes.
- 4) Consists of (i) 100,000 shares of EIP Common Stock and (ii) 826,541 shares of common stock issuable upon the conversion of EIP Convertible Notes held by PENSCO Trust Company, LLC, Custodian FBO Frank E. Zavrl ROTH IRA; (i) 1,380,610 shares of EIP Common Stock underlying shares of EIP's Series A-2 preferred stock and (ii) 109,701 shares of EIP Common Stock issuable upon the conversion of EIP Convertible Notes held by Paula Zavrl Delaware Dynasty Trust. Mr. Zavrl is the trust investment manager of the Paula Zavrl Delaware Dynasty Trust.
- 5) Consists of (i) 9,102 shares of EIP Common Stock and (ii) 109,701 shares of EIP Common Stock issuable upon the conversion of EIP Convertible Notes.

Treatment of EIP Options

Under the Merger Agreement, at the Effective Time, each EIP Option outstanding and unexercised as of immediately prior to the Effective Time, whether or not vested, shall be converted into and become an option to purchase that number of shares of Diffusion Common Stock equal to the product obtained by multiplying (i) the number of shares of EIP common stock that were subject to such EIP Option immediately prior to the Effective Time by (ii) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Diffusion Common Stock.

The following table presents certain information concerning the outstanding EIP Options held by EIP's directors and current executive officers, as of April 1, 2023:

Option holder	Grant Date	Expiration Date	Exercise Price	Number of Shares of EIP Common Stock Underlying Option as of April 1, 2023	Number of Shares of EIP Common Stock Underlying Option Vested as of April 1, 2023
Kelly Blackburn, MHA	5/29/2018	5/29/2028	\$2.28	72,000	72,000
	3/4/2019	3/4/2029	\$3.19	48,000	48,000
	12/16/2019	12/16/2029	\$3.00	40,000	32,500
	3/12/2021	3/12/2031	\$4.01	60,000	30,000
Jeff Poulton	05/29/2018	05/29/2028	\$2.28	60,000	60,000
	12/16/2019	12/16/2029	\$3.00	30,000	24,375
	3/12/2021	3/12/2031	\$4.01	20,000	10,000
	03/10/2022	03/10/2032	\$2.24	20,000	5,000
Marwan Sabbagh	9/24/2021	9/24/2031	\$4.01	40,000	15,000
Frank Zavrl	05/29/2018	05/29/2028	\$2.28	60,000	60,000
	12/16/2019	12/16/2029	\$3.00	30,000	24,375
	3/12/2021	3/12/2031	\$4.01	20,000	10,000
	03/10/2022	03/10/2032	\$2.24	20,000	5,000

The foregoing discussion of the interests of the EIP directors and officers in the Merger does not reflect the effect of the Reverse Split and is not adjusted to reflect the effect of the Exchange Ratio.

Management Following the Merger

As described elsewhere in this proxy statement/prospectus/information statement, including in the section titled “*Management Following the Merger*” beginning on page 247, certain of EIP directors and executive officers are expected to become the directors and executive officers of Diffusion upon the Closing.

Limitations of Liability and Indemnification

In addition to the indemnification required by Diffusion's certificate of incorporation, as amended, and bylaws, as amended, Diffusion has entered into indemnification agreements with each of its directors and officers. These agreements provide for the indemnification of such persons for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were officers, directors or agents of Diffusion, or by reason of anything done or not done in their capacities as such. Diffusion believes that the indemnification provisions in its certificate of incorporation, as amended, and bylaws, as amended, and its indemnification agreements are necessary to attract and retain qualified persons as directors and officers of Diffusion.

Additionally, under the Merger Agreement, from date on which the effective time of the Merger occurs through the sixth anniversary thereof, the combined company and EIP, as the surviving corporation in the merger, have agreed to indemnify and hold harmless each person who is now, or has been at any time prior to March 30, 2023, or who becomes prior to the Effective Time, a director or officer (or equivalent) of Diffusion, EIP or any of their respective subsidiaries (each, an “Indemnified Party”), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was a director or officer of Diffusion, EIP or any of their respective subsidiaries or arising out of or pertaining to matters existing or occurring at or prior to the Effective Time, to the fullest extent permitted under applicable law. In addition, each such person is entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from each of Diffusion and EIP, as the surviving corporation in the Merger, jointly and severally, upon receipt by either entity of a request therefor.

Under the Merger Agreement, the provisions of Diffusion’s and its subsidiaries’ organizational documents with respect to indemnification, advancement of expenses and exculpation of Indemnified Parties are not permitted be amended, modified or repealed for a period of six years from the date on which effective time of the Merger occurs in a manner that would adversely affect their rights thereunder. The Merger Agreement requires that the organizational documents of Diffusion and its subsidiaries (including EIP as the surviving corporation in the Merger) contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of the Indemnified Parties than are presently set forth in those organizational documents.

The Merger Agreement also requires Diffusion to maintain directors’ and officers’ liability insurance policies commencing on the closing time of the Merger, on commercially available terms and conditions with coverage limits customary for U.S. public companies similarly situated to Diffusion. In addition, to the extent required as a result of the termination of coverage under Diffusion’s directors’ and officers’ liability insurance policy in effect prior to the closing of the Merger, Diffusion is required to purchase prior to the effective time of the Merger, a six-year prepaid “tail policy.” The Merger Agreement also requires that Diffusion add EIP and its subsidiaries as additional insureds solely in their capacity as Diffusion’s successors in interest on the tail policy on Diffusion’s behalf, at EIP’s request and at EIP’s expense.

Merger Consideration and Exchange Ratio

For a discussion of the merger consideration and the Exchange Ratio, please see the section titled “*The Merger Agreement — Merger Consideration and Exchange Ratio*” beginning on page 146.

Treatment of Diffusion Stock Options, Restricted Stock Units and Warrants

Following the Merger, assuming no Reverse Split, all outstanding and unexercised options to purchase shares of Diffusion Common Stock, outstanding restricted stock units and outstanding warrants to purchase Diffusion Common Stock will remain in effect and outstanding in accordance with their terms.

Treatment of EIP Stock Options

Under the terms of the Merger Agreement, Diffusion will assume the EIP Plan, and all rights with respect to each outstanding option to purchase EIP Common Stock in accordance with its terms and the terms of the stock option agreement by which such option is evidenced. Accordingly, at the Effective Time, each option to purchase shares of EIP Common Stock granted under the EIP Plan that is outstanding and unexercised immediately prior to the effective time of the Merger, whether or not vested, without any action on the part of the holder thereof, will be converted into an option to purchase shares of Diffusion Common Stock, on the same terms and conditions as were applicable to such EIP Option immediately prior to the effective time of the Merger.

All rights with respect to EIP Common Stock under such options assumed by Diffusion will thereupon be converted into rights with respect to a number of shares of Diffusion Common Stock determined by multiplying (1) the number of shares of EIP Common Stock that were subject to such option, as in effect immediately prior to the effective time, by (2) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Diffusion Common Stock, at an exercise price per share determined by dividing (A) the per share exercise price of EIP Common Stock subject to such option, as in effect immediately prior to the effective time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent. Any restriction on the exercise of any EIP stock option assumed by Diffusion will continue in full force and effect and the term, exercisability, vesting schedule and any other provisions of such EIP stock option will otherwise remain unchanged.

Treatment of EIP Warrants

Upon the effectiveness of the Merger, all EIP warrants outstanding immediately prior to the Merger will be assumed by Diffusion and become exercisable (1) for a number of shares of Diffusion Common Stock equal to the number of shares of EIP Common Stock subject to such warrant immediately prior to the effectiveness of the Merger multiplied by the Exchange Ratio (rounding down to the nearest whole share) and (2) at an exercise price per share of Diffusion Common Stock equal to the exercise price per share of EIP Common Stock applicable immediately prior to the effectiveness of the Merger divided by the Exchange Ratio (rounding up to the nearest whole cent). Any restriction on the exercise of any of such EIP warrants assumed by Diffusion will continue in full force and effect in accordance with its terms.

Management Following the Merger

Following the Effective Time, the combined company's directors and executive officers are expected to be composed of members of the following current Diffusion and EIP boards of directors and management teams:

Name	Position(s)
Directors	
Sylvie Grégoire, PharmD.	Chair of the Board of Directors
John Alam, M.D.	Director
Robert J. Cobuzzi, Jr., Ph.D.	Director
Jane Hollingsworth, J.D.	Director
Jeff Poulton	Director
Marwan Sabbagh, M.D.	Director
Frank Zavrl	Director
Executive Officers	
John Alam, MD	Chief Executive Officer
Robert J. Cobuzzi, Jr., Ph.D.	Chief Operating Officer
William Tanner, Ph.D.	Chief Financial Officer
Kelly Blackburn, MHA	Senior Vice President, Clinical Development
William Elder	General Counsel and Corporate Secretary

Merger Expenses

Except as otherwise expressly provided in the Merger Agreement, all costs and expenses incurred in connection with the Merger Agreement and the transactions contemplated thereby will be paid by the party incurring such expense, except that 50% all fees and expenses paid (1) to a proxy solicitor, filing agent, and/or printer, (2) in connection with filing and mailing this proxy statement/prospectus/information statement, and any amendments and supplements hereto and (3) the Nasdaq fees associated with the Nasdaq initial listing application, to the extent required by Nasdaq Marketplace Rule 5110 to be filed in connection with the Merger, will be added to the calculation of Diffusion's net cash for purposes of calculating the Exchange Ratio.

Effective Time of the Merger

The Merger Agreement requires the parties to consummate the Merger as promptly as practicable (and in any event within three business days) after all of the conditions to the closing of the Merger contained in the Merger Agreement are satisfied or waived, including the adoption of the Merger Agreement by the EIP stockholders and the approval by the Diffusion stockholders of the Stock Issuance Proposal. The Merger will become effective upon the filing of a certificate of merger with the Secretary of State of the State of Delaware or at such later time as is agreed by Diffusion and EIP and specified in the certificate of merger. Neither Diffusion nor EIP can predict the exact timing of the closing of the Merger.

Regulatory Approvals

Diffusion must comply with applicable federal and state securities laws and the rules and regulations of the Nasdaq Capital Market in connection with the issuance of shares of Diffusion Common Stock and the filing of this proxy statement/prospectus/information statement with the SEC. Diffusion does not intend to seek any regulatory approval from antitrust authorities to consummate the transactions contemplated by the Merger Agreement.

Tax Treatment of the Merger

Subject to the limitations and qualifications described in the section titled “*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*” of this proxy statement/prospectus/information statement, in the opinion of Mintz, counsel to EIP, the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code. This opinion is based on facts and representations contained in representation letters provided by EIP, Diffusion and Merger Sub and on customary factual assumptions, and further assumes that the Merger is completed in the manner set forth in the Merger Agreement and the registration statement on Form S-4 of which this proxy statement/prospectus/information statement forms a part. For a description of certain of the considerations regarding U.S. federal tax consequences of the Merger, see the section titled “*The Merger — Certain Material U.S. Federal Income Tax Consequences of the Merger*” below.

Certain Material U.S. Federal Income Tax Consequences of the Merger

The following is a discussion of certain material U.S. federal income tax consequences of the Merger applicable to U.S. Holders (as defined below) who exchange their EIP Common Stock for Diffusion Common Stock in the Merger, but does not purport to be a complete analysis of all potential tax effects.

This discussion and the discussion of tax consequences elsewhere in this proxy statement/prospectus/information statement are limited to U.S. Holders who hold their EIP Common Stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This summary does not address all aspects of U.S. federal income taxation that may be relevant to U.S. Holders in light of their particular circumstances or to U.S. Holders who may be subject to special tax treatment under the Code, including, without limitation, dealers in securities, commodities or foreign currency; banks, thrifts, insurance companies, and other financial institutions; traders that mark-to-market their securities; tax-exempt organizations or governmental organizations; regulated investment companies; real estate investment trusts; tax-deferred or other retirement accounts; persons whose functional currency is not the U.S. dollar; persons who hold EIP Common Stock as part of a “straddle,” “hedge,” “conversion transaction” or other risk reduction transaction; persons who hold or receive EIP Common Stock pursuant to the exercise of compensatory stock options, the vesting of previously restricted shares of stock or otherwise as compensation; persons holding EIP Common Stock who exercise dissenters’ rights; any entity or arrangement that is treated as a partnership or other pass-through entity for U.S. federal income tax purposes; “expatriated entities”; or certain former citizens or long-term residents of the United States.

This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the IRS in effect as of the date of the Merger, all of which are subject to change, possibly with retroactive effect, or differing interpretations. Neither EIP nor Diffusion have sought any ruling from the IRS with respect to the statements made and the conclusions reached in this discussion, and there can be no assurance that the IRS will agree with these statements and conclusions. The effects of other U.S. federal tax laws, such as estate and gift tax laws, the alternative minimum tax and the 3.8% tax on net investment income, and any applicable state, local, or foreign tax laws or the tax consequences of events occurring prior to, concurrently with or after the Merger (whether or not such transactions are in connection with the Merger) are not discussed.

Each U.S. Holder is urged to consult its own tax advisor with regard to the Merger and the application of U.S. federal income tax laws, as well as the laws of any state, local or foreign taxing jurisdictions, to its particular situation.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of EIP Common Stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;

- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if either a court within the United States is able to exercise primary supervision over the administration of such trust and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of such trust, or the trust has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person for U.S. federal income tax purposes.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold EIP Common Stock through such entities. If a partnership (or other entity or arrangement treated as a partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of any EIP Common Stock, the U.S. federal income tax treatment of a partner or member in such partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity and its partners or members. Partnerships or other pass-through entities or arrangements holding EIP Common Stock and partners or members in such entities or arrangements are urged to consult their own tax advisors. U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE MERGER ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Subject to the qualifications and assumptions described in this proxy statement/prospectus/information statement, including as set forth in the U.S. federal income tax opinion filed as Exhibit 8.1 herewith, in the opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel to EIP, the Merger will be treated for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code. This opinion is based on facts and representations contained in representation letters provided by EIP, Diffusion and Merger Sub and on customary factual assumptions, and further assumes that the Merger is completed in the manner set forth in the Merger Agreement and the registration statement on Form S-4 of which this proxy statement/prospectus/information statement forms a part. Assuming such treatment, it is expected that the U.S. federal income tax consequences to U.S. Holders of EIP Common Stock will be as follows:

- a U.S. Holder will not recognize gain or loss upon the exchange of EIP Common Stock for Diffusion Common Stock pursuant to the merger, except to the extent of cash received in lieu of a fractional share of Diffusion Common Stock as described below;
- a U.S. Holder who receives cash in lieu of a fractional share of Diffusion capital stock in the merger generally will recognize capital gain or loss in an amount equal to the difference between the amount of cash received instead of a fractional share and the U.S. Holder's tax basis allocable to such fractional share;
- a U.S. Holder's aggregate tax basis for the shares of Diffusion Common Stock received in the Merger will equal the U.S. Holder's aggregate tax basis in the shares of EIP Common Stock surrendered upon the closing of the Merger, decreased by the amount of any tax basis allocable to a fractional share for which cash is received; and
- the holding period of the shares of Diffusion Common Stock received by a U.S. Holder in the Merger will include the holding period of the U.S. Holder's shares of EIP Common Stock surrendered in exchange therefor.

Capital gains or losses recognized in the Merger as described above, if any, generally will constitute long-term capital gain or loss if the U.S. Holder's holding period in the EIP Common Stock surrendered in the Merger is more than one year as of the effective date of the Merger. The deductibility of capital losses is subject to limitations. In addition, for purposes of the above discussion of the bases and holding periods for shares of EIP Common Stock and Diffusion Common Stock, U.S. Holders who acquired different blocks of EIP Common Stock at different times for different prices must calculate their gains and losses and holding periods separately for each identifiable block of such stock exchanged in the Merger.

U.S. Holders who owned at least 1% (by vote or value) of the total outstanding stock of EIP and U.S. Holders with a basis in their EIP Common Stock of \$1,000,000 or more are required to attach a statement to their tax returns for the year in which the Merger is consummated that contains the information listed in Treasury Regulation Section 1.368-3(b). Such statement must include the U.S. Holder's tax basis in the U.S. Holder's EIP Common Stock and the fair market value of such stock.

Tax Consequences if the Merger Failed to Qualify as a Reorganization

If the Merger fails to qualify as a reorganization within the meaning of Section 368(a) of the Code, then a U.S. Holder would recognize gain or loss upon the exchange of EIP Common Stock for Diffusion Common Stock equal to the difference between the fair market value, at the time of the Merger, of the Diffusion Common Stock received in the Merger (including any cash received in lieu of a fractional share) and such U.S. Holder's tax basis in the EIP Common Stock surrendered in the Merger. Such gain or loss would be long-term capital gain or loss if the EIP Common Stock was held for more than one year at the time of the Merger. In such event, the tax basis of Diffusion Common Stock received in the Merger would equal its fair market value at the time of the Merger and the holding period of such Diffusion Common Stock would commence the day after the Merger.

Reporting Requirements

U.S. Holders who owned at least 1% (by vote or value) of the total outstanding stock of EIP and U.S. Holders with a basis in their EIP Common Stock of \$1,000,000 or more are required to attach a statement to their tax returns for the year in which the Merger is consummated that contains the information listed in Treasury Regulation Section 1.368-3(b). Such statement must include the U.S. Holder's tax basis in the U.S. Holder's EIP Common Stock and the fair market value of such stock.

Information Reporting and Backup Withholding

A U.S. Holder of shares of EIP Common Stock may be subject to information reporting and backup withholding on cash paid in lieu of fractional shares, unless the U.S. Holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. Holder fails to furnish a correct taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Each U.S. Holder of shares of EIP Common Stock should properly complete and sign, and deliver, an IRS Form W-9 in order to provide the information and certification necessary to avoid backup withholding, or otherwise establish an applicable exemption in a manner acceptable to the paying agent. U.S. Holders of shares of EIP Common Stock should consult their own tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption. Backup withholding is not an additional tax. Any amounts withheld will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Nasdaq Stock Market Listing

Diffusion Common Stock currently is listed on the Nasdaq Capital Market under the symbol "DDFN." Diffusion has agreed to use its commercially reasonable efforts (1) to maintain its existing listing on the Nasdaq Capital Market until the Effective Time and obtain approval of the listing of the combined company on the Nasdaq Capital Market, (2) to prepare and submit a notification form for the listing of the shares of Diffusion Common Stock to be issued in the Merger and cause such shares to be approved for listing (subject to official notice of issuance), (3) to effect the Reverse Split and (4) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial Nasdaq Listing Application for the Diffusion Common Stock on the Nasdaq Capital Market and to cause such listing application to be conditionally approved prior to the effective time of the Merger.

In addition, under the Merger Agreement, each of Diffusion's and EIP's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the Merger, of various conditions, including that the shares of Diffusion Common Stock to be issued in the Merger have been approved for listing on Nasdaq as of the Effective Time. In the event Diffusion and EIP waive this condition and consummate the Merger without the shares of Diffusion Common Stock to be issued in the Merger having been approved for the listing on Nasdaq, Diffusion and EIP anticipate that Nasdaq would commence delisting proceedings. Please see the section titled "*Risk Factors — Risks Related to the Merger — If Nasdaq does not approve Diffusion's listing application for the combined company and the parties waive the Nasdaq closing condition and continue with the Merger, Diffusion may be subject to delisting.*"

If the closing of the Merger occurs and the Nasdaq Listing Application is accepted, Diffusion anticipates that the common stock of the combined company will be listed on the Nasdaq Capital Market following the Effective Time under a new trading symbol “CRVO.”

Anticipated Accounting Treatment

The Merger will be treated by Diffusion as a reverse recapitalization in accordance with GAAP. EIP has been determined to be the acquiring company in the Merger for financial reporting purposes based upon several factors, including: (i) former EIP securityholders are expected to own a substantial majority of the Diffusion Common Stock outstanding immediately following the Effective Time, (ii) EIP is entitled to designate the majority (five of seven) of initial members of the board of directors of the combined company, and (iii) EIP’s current senior management will hold the majority (three of five) positions in the senior management of the combined company. As a result of EIP being treated as the acquiring company for financial reporting purposes, if the Merger is consummated, among other things, the historical financial statements of EIP will become the historical consolidated financial statements of the combined company.

Appraisal Rights and Dissenters’ Rights

If the Merger is completed, EIP stockholders who do not deliver a written consent approving the Merger are entitled to appraisal rights under Section 262 of the DGCL (“Section 262”), provided that they comply with the conditions established by Section 262. Holders of Diffusion Common Stock are not entitled to appraisal rights under Delaware law in connection with the Merger.

The discussion below is not a complete summary regarding EIP stockholders’ and beneficial owners’ appraisal rights under Delaware law and is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this proxy statement/prospectus/information statement as *Annex E*. Stockholders intending to exercise appraisal rights should carefully review *Annex E* and may be accessed without subscription or cost at the following publicly available website: <https://delcode.delaware.gov/title8/c001/sc09/index.html#262>. All references in Section 262 of the DGCL and this summary to “stockholder” are to the record holder of the shares of EIP Common Stock as to which appraisal rights are asserted. All references in this summary to “beneficial owner” means the beneficial owner of shares of EIP Common Stock held either in voting trust or by a nominee on behalf of such person. Any holder of record or beneficial owner of shares of EIP Common Stock who are intending to exercise appraisal rights or who wish to preserve his, her or its right to do so should carefully review *Annex E* and should consult his, her or its legal advisors. Failure to follow precisely any of the statutory procedures set forth in *Annex E* may result in the termination or waiver of these rights. This summary does not constitute legal or other advice, nor does it constitute a recommendation that EIP stockholders exercise their appraisal rights under Delaware law.

Under Section 262, where a merger is adopted by stockholders by written consent in lieu of a meeting of stockholders pursuant to Section 228 of the DGCL, either the constituent corporation before the effective date of the merger or the surviving corporation, within 10 days after the effective date of such merger, must notify each stockholder and beneficial owner of the constituent corporation entitled to appraisal rights of the approval of such merger, the effective date of the merger, that appraisal rights are available, and must include in each such notice a copy of Section 262 of the DGCL or information directing the stockholders to a publicly available electronic resource at which this section may be accessed without subscription or cost.

If the Merger is completed, within 10 days after the effective date of the Merger, EIP will notify each stockholder and beneficial owner who properly demanded appraisal rights under Section 262 of the DGCL and has not voted for the Merger and is entitled to appraisal that the Merger has been approved and the effective date of the Merger. Record holders and beneficial owners of shares of EIP Common Stock who desire to exercise their appraisal rights must deliver a written demand for appraisal to EIP within 20 days after the date of mailing of that notice, and that stockholder must not have delivered a written consent approving the Merger. A demand for appraisal made by a record holder of shares of EIP Common Stock must reasonably inform EIP of the identity of the stockholder and that such stockholder intends thereby to demand appraisal of the shares of EIP Common Stock held by such stockholder. Any such demand for appraisal should be executed by or on behalf of the holder of record of the shares for which appraisal is demanded, fully and correctly, as the stockholder’s name appears on EIP’s books and records and state that the person intends thereby to demand appraisal of the stockholder’s shares of EIP Common Stock in connection with the Merger. The demand may also be made by a beneficial owner of shares of EIP Common Stock if, in addition to otherwise satisfying the foregoing requirements, (i) such beneficial owner continuously owns such shares through the Effective Time and otherwise satisfies the requirements for appraisal applicable to a stockholder of record under subsection (a) of Section 262 of the DGCL and (ii) the demand made by such beneficial owner reasonably identifies the holder of record of such shares for which the demand is made, is accompanied by documentary evidence of such beneficial owner’s beneficial ownership of such shares and a statement that such documentary evidence is a true and correct copy of what it purports to be, and provides an address at which such beneficial owner consents to receive notices and to be set forth on the verified list described below. Alternatively, beneficial owners of shares of EIP Common Stock may have the holder of record of such shares submit the required demand in respect of such shares.

Failure to deliver a written consent approving the Merger will not in and of itself constitute a written demand for appraisal satisfying the requirements of Section 262. All demands for appraisal should be addressed to EIP, 20 Park Plaza, Suite 424, Boston, MA 02116, Attn: John Alam, Email: jalam@eippharma.com, and should be executed by, or on behalf of, the record holder of shares of EIP Common Stock. ALL DEMANDS MUST BE RECEIVED BY EIP WITHIN 20 DAYS AFTER THE DATE EIP MAILS A NOTICE TO ITS STOCKHOLDERS ENTITLED THERETO NOTIFYING THEM THAT THE MERGER HAS BEEN APPROVED, THE EFFECTIVE DATE OF THE MERGER AND THAT APPRAISAL RIGHTS ARE AVAILABLE TO ANY STOCKHOLDER WHO HAS NOT APPROVED THE MERGER.

If you fail to deliver a written demand for appraisal within the time period specified above, you will be entitled to receive the merger consideration for your shares of EIP Common Stock as provided for in the Merger Agreement, but you will have no appraisal rights with respect to your shares of EIP Common Stock.

To be effective, a demand for appraisal by a holder of shares of EIP Common Stock must be made by, or in the name of, the registered stockholder, fully and correctly, as the stockholder's name appears on the stockholder's stock certificate(s). Beneficial owners who do not also hold the shares of record may not directly make appraisal demands to EIP. The beneficial owner must, in these cases, have the registered owner, such as a broker, bank or other custodian, submit the required demand in respect of those shares. If shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, execution of a demand for appraisal should be made by or for the fiduciary; and if the shares are owned of record by more than one person, as in a joint tenancy or tenancy in common, the demand should be executed by or for all joint owners. An authorized agent, including an authorized agent for two or more joint owners, may execute the demand for appraisal for a stockholder of record; however, the agent must identify the record owner or owners and expressly disclose the fact that, in executing the demand, he or she is acting as agent for the record owner. A record owner, such as a broker, who holds shares as a custodian for others, may exercise the record owner's right of appraisal with respect to the shares held for one or more beneficial owners, while not exercising this right for other beneficial owners. In that case, the written demand should state the number of shares as to which appraisal is sought. Where no number of shares is expressly mentioned, the demand will be presumed to cover all shares held in the name of the record owner. In addition, the stockholder must continuously hold the shares of record from the date of making the demand through the Effective Time.

If you hold your shares of EIP Common Stock in a brokerage account or in other custodian form and you wish to exercise appraisal rights, you should consult with your bank, broker or other custodian to determine the appropriate procedures for the making of a demand for appraisal by the custodian.

At any time within 60 days after the Effective Time, any person who has demanded an appraisal, but has neither commenced an appraisal proceeding or joined an appraisal proceeding as a named party, has the right to withdraw such person's demand and accept the terms of the merger by delivering a written withdrawal to EIP. No appraisal proceeding in the Delaware Court of Chancery (the "Delaware Court") will be dismissed as to any person without the approval of the Delaware Court, with such approval conditioned upon such terms as the Delaware Court deems just, including without limitation, a reservation of jurisdiction for any application to the Delaware Court made pursuant to Section 262(j) for expenses, including, without limitation, reasonable attorneys' fees and the fees and expenses of experts, to be charged pro rata against the value of all shares entitled to appraisal, provided, however, that this provision will not affect the right of any EIP stockholder or beneficial owner who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder's or beneficial owner's demand for appraisal and to accept the merger consideration within 60 days after the effective time of the Merger.

If, following a demand for appraisal, you have withdrawn your demand for appraisal in accordance with Section 262, you will have the right to receive the merger consideration for your shares of EIP Common Stock.

Within 120 days after the effective date of the merger, any stockholder who has delivered a demand for appraisal in accordance with Section 262 will, upon written request to the surviving corporation, be entitled to receive a written statement setting forth the aggregate number of shares not voted in favor of the Merger Agreement and with respect to which demands for appraisal rights have been received and the aggregate number of holders of these shares. This written statement will be mailed to the requesting stockholder within 10 days after the stockholder's written request is received by the surviving corporation or within ten days after expiration of the period for delivery of demands for appraisal, whichever is later. Within 120 days after the effective date of the Merger, either the surviving corporation or any stockholder who has delivered a demand for appraisal in accordance with Section 262 may file a petition in the Delaware Court of Chancery demanding a determination of the fair value of the shares held by all such stockholders. Upon the filing of the petition by a stockholder, service of a copy of the petition must be made upon the surviving corporation. The surviving corporation has no obligation to file a petition in the Delaware Court of Chancery in the event there are dissenting stockholders, and EIP, which is expected to be the surviving corporation, has no present intent to file a petition in the Delaware Court of Chancery. Accordingly, the failure of a stockholder to file a petition within the period specified could nullify the stockholder's previously written demand for appraisal.

If a petition for appraisal is duly filed by a stockholder and a copy of the petition is delivered to the surviving corporation, the surviving corporation will then be obligated, within 20 days after receiving service of a copy of the petition, to provide the Delaware Court of Chancery with a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached by the surviving corporation. After notice to dissenting stockholders who demanded appraisal of their shares, the Delaware Court of Chancery is empowered to conduct a hearing upon the petition, and to determine those stockholders who have complied with Section 262 and who have become entitled to the appraisal rights provided thereby. The Delaware Court of Chancery may require the stockholders who have demanded appraisal for their shares to submit their stock certificates to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with that direction, the Delaware Court of Chancery may dismiss the proceedings as to that stockholder.

After determination of the stockholders entitled to appraisal of their shares, the Delaware Court of Chancery will appraise the "fair value" of the shares owned by those stockholders. This value will be exclusive of any element of value arising from the accomplishment or expectation of the merger, but may include a fair rate of interest, if any, upon the amount determined to be the fair value. When the value is determined, the Delaware Court of Chancery will direct the payment of the value, with interest thereon accrued during the pendency of the proceeding, if the Delaware Court of Chancery so determines, to the stockholders entitled to receive the same, upon surrender by the holders of the certificates representing those shares.

In determining fair value, and, if applicable, a fair rate of interest, the Delaware Court of Chancery is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that "proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court" should be considered, and that "fair price obviously requires consideration of all relevant factors involving the value of a company."

Section 262 provides that fair value is to be "exclusive of any element of value arising from the accomplishment or expectation of the merger." In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that this exclusion is a "narrow exclusion [that] does not encompass known elements of value," but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court construed Section 262 to mean that "elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered."

You should be aware that the fair value of your shares as determined under Section 262 could be more than, the same as, or less than the value that you are entitled to receive under the terms of the Merger Agreement.

Costs of the appraisal proceeding may be imposed upon the surviving corporation and the stockholders participating in the appraisal proceeding by the Delaware Court of Chancery as the Court deems equitable in the circumstances. Upon the application of a stockholder, the Delaware Court of Chancery may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorneys' fees and the fees and expenses of experts, to be charged pro rata against the value of all shares entitled to appraisal. In the absence of such a determination of assessment, each party bears its own expenses. Any stockholder who had demanded appraisal rights will not, after the Effective Time, be entitled to vote shares subject to that demand for any purpose or to receive payments of dividends or any other distribution with respect to those shares, other than with respect to payment as of a record date prior to the Effective Time; however, if no petition for appraisal is filed within 120 days after the Effective Time, or if the stockholder delivers a written withdrawal of his or her demand for appraisal and an acceptance of the terms of the merger within 60 days after the Effective Time, then the right of that stockholder to appraisal will cease and that stockholder will be entitled to receive the merger consideration for shares of his or her EIP Common Stock pursuant to the Merger Agreement. Any withdrawal of a demand for appraisal made more than 60 days after the Effective Time may only be made with the written approval of the surviving corporation. No appraisal proceeding in the Delaware Court of Chancery will be dismissed as to any stockholder without the approval of the court.

Failure to follow the steps required by Section 262 for perfecting appraisal rights may result in the loss of appraisal rights. In view of the complexity of Section 262, stockholders who may wish to dissent from the merger and pursue appraisal rights should consult their legal advisors.

THE MERGER AGREEMENT

The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached as Annex A to this proxy statement/prospectus/information statement and is incorporated by reference into this proxy statement/prospectus/information statement. The Merger Agreement has been attached to this proxy statement/prospectus/information statement to provide you with information regarding its terms. It is not intended to provide any other factual information about Diffusion, EIP, or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the Merger and the terms and conditions of the Merger Agreement.

The Merger Agreement contains representations and warranties that Diffusion and Merger Sub, on the one hand, and EIP, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While Diffusion and EIP do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about Diffusion or EIP, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Diffusion and EIP, and are modified by the disclosure schedules.

General

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of Diffusion formed in connection with the Merger, will merge with and into EIP, with EIP surviving as a wholly-owned subsidiary of the combined company. At the Effective Time, Diffusion will be renamed “CervoMed Inc.” and, subject to satisfying Nasdaq’s initial listing standards, expects to trade on the Nasdaq Capital Market under the symbol “CRVO.”

Merger Consideration and Exchange Ratio

Merger Consideration

Immediately prior to the Effective Time, each outstanding share of EIP Preferred Stock will be converted into one share of EIP Common Stock. At the Effective Time, other than certain excluded shares and dissenting shares, each share of EIP Common Stock will be converted into the right to receive a number of shares of Diffusion Common Stock equal to the Exchange Ratio described below subject to adjustment to account for the effect of a reverse stock split of outstanding Diffusion Common Stock, within a range of one new share for not less than and not greater than shares outstanding, with such ratio to be mutually agreed upon by Diffusion and EIP prior to the Effective Time, as discussed in this proxy statement/prospectus/information statement, and further adjusted based on Diffusion’s net cash immediately prior to the Effective Time. No fractional shares of Diffusion Common Stock will be issued in connection with the Merger. Instead, each former EIP stockholder who would otherwise be entitled to receive a fraction of a share of Diffusion Common Stock, after aggregating all fractional shares of Diffusion Common Stock issuable to such stockholder, will be entitled to receive in cash the dollar amount, rounded to the nearest whole cent, without interest, determined by multiplying such fraction by the volume weighted average closing trading price of a share of Diffusion Common Stock on Nasdaq for the ten consecutive trading days ending at the close of business ending on the second trading day prior to the closing date of the Merger.

As noted above, each share of EIP capital stock (other than EIP Common Stock) and each share of EIP capital stock held in the treasury of EIP or owned, directly or indirectly, by Diffusion, Merger Sub or any subsidiary of EIP, immediately prior to the Effective Time will automatically be cancelled and will cease to exist, and no consideration will be delivered in exchange therefor. These shares are excluded from the receipt of consideration in the Merger. In addition, shares of the EIP capital stock (other than the excluded shares) that are outstanding immediately prior to the Effective Time and held by a holder who is entitled to demand and has properly demanded appraisal for such shares of EIP capital stock in accordance with Section 262 of the Delaware General Corporation Law will not be converted into or be exchangeable for the right to receive a portion of the Merger consideration unless and until such holder fails to perfect or withdraws or otherwise loses such holder’s right to appraisal and payment under the DGCL.

Under the Merger Agreement, outstanding shares of EIP Preferred Stock are required to be converted prior to the Effective Time on a one-for-one basis into shares of EIP Common Stock such that no shares of EIP preferred stock will be issued and outstanding prior to the Effective Time after giving effect to such conversion. In addition, the outstanding EIP Convertible Notes are required to be converted into shares of EIP Common Stock at or prior to the Effective Time and treated consistent with the other shares of EIP Common Stock.

Exchange Ratio

The Exchange Ratio is calculated using a formula intended to allocate to existing EIP equity holders (on a fully-diluted basis), a percentage of the combined company. As of the date of the Merger Agreement, it was anticipated that, after giving effect to the transactions contemplated thereby, the Exchange Ratio would be approximately 0.1860 pre-split shares of Diffusion Common Stock for each share of EIP Common Stock, subject to adjustment to account for the effect of the Reverse Split, if any. These estimates are subject to adjustment prior to the closing of the Merger, including (i) adjustments to account for the issuance of any additional shares of EIP capital stock or Diffusion Common Stock, as applicable, prior to the consummation of the Merger, (ii) an upward adjustment to the extent that Diffusion's net cash at the Effective Time is less than \$13.5 million (and as a result, Diffusion securityholders could own less, and EIP equity holders could own more, of the combined company), or (iii) a downward adjustment to the extent that Diffusion's net cash at the Effective Time is more than \$14.5 million (and as a result, Diffusion securityholders could own more, and EIP equity holders could own less, of the combined company).

Immediately after the consummation of the Merger, based on the Exchange Ratio, it is expected that existing EIP equity holders are expected to own, or hold rights to acquire, approximately 77.25% of the fully-diluted EIP Common Stock and existing Diffusion equity holders are expected to own approximately 22.75% of the fully-diluted Diffusion Common Stock. Such percentages are subject to adjustment based on the final Exchange Ratio as set forth in the Merger Agreement.

The Exchange Ratio formula is calculated as the quotient (rounded to four decimal places) obtained by dividing the number of EIP merger shares by the EIP fully-diluted outstanding shares, where:

- EIP merger shares means the number of shares equal to (1) the post-closing Diffusion shares, *minus* (2) the fully-diluted Diffusion outstanding shares;
- EIP fully-diluted outstanding shares is the total number of shares of EIP capital stock outstanding immediately prior to the Effective Time expressed on a fully-diluted and as-converted to EIP Common Stock basis and assuming, without limitation or duplication, (i) the cashless exercise of all EIP options outstanding as of immediately prior to the Effective Time with an exercise price less than the Diffusion closing price (on a converted to EIP Common Stock basis), and (ii) issuance of shares of EIP Common Stock and EIP Preferred Stock in respect of all warrants, restricted stock units or other similar rights to receive such shares (assuming cashless exercise using the Diffusion closing price and on a converted to EIP Common Stock basis), whether conditional or unconditional and including any outstanding warrants, restricted stock units or other similar rights (including the EIP Convertible Notes). No out-of-the-money EIP options are included in the total number of EIP capital stock outstanding.
- The Diffusion closing price means the volume weighted average closing trading price of a share of Diffusion Common Stock on Nasdaq for the five consecutive trading days ending five trading days prior to the date on which the Effective Time occurs.
- Post-closing Diffusion shares is the quotient (rounded to the nearest whole share) determined by dividing (i) the fully-diluted Diffusion outstanding shares by (ii) the Diffusion allocation percentage.

- The fully-diluted Diffusion outstanding shares means the total number of shares of Diffusion Common Stock outstanding immediately prior to the Effective Time expressed on a fully-diluted basis and assuming, without limitation or duplication, (i) the cashless exercise of all Diffusion options and warrants outstanding as of immediately prior to the Effective Time with an exercise price less than the Diffusion closing price, (ii) the settlement of each Diffusion restricted stock unit that is outstanding immediately prior to the Effective Time for an equivalent number of shares of Diffusion Common Stock, and (iii) the issuance of shares of Diffusion Common Stock in respect of all other warrants, restricted stock units or other similar rights to receive such shares (assuming cashless exercise using the Diffusion closing price in the case of warrants and other similar rights), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Diffusion Common Stock reserved for issuance). The amounts are to be calculated after giving effect to the proposed Reverse Split, if applicable. No out-of-the-money Diffusion options or warrants will be included as Diffusion outstanding shares.
- The Diffusion allocation percentage is 0.2275; provided, however, to the extent that the net cash determined pursuant to the Merger Agreement (i) is less than \$13.5 million, then 0.2275 will be reduced by 0.0005 for each \$100,000 that the net cash, as determined, is less than \$13.5 million or (ii) is more than \$14.5 million, then 0.2275 will be increased by 0.0005 for each \$100,000 that the net cash as so determined is more than \$14.5 million.
- EIP's allocation percentage is 1.00 minus the Diffusion allocation percentage.

The Merger Agreement does not include a price-based termination right. Accordingly, the market value of the shares of Diffusion Common Stock issued pursuant to the Merger will depend on the market value of the shares of Diffusion Common Stock at the time the Merger closes and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement.

The following table illustrates how the Exchange Ratio and post-Merger equity ownership of the combined company by the former Diffusion stockholders and former EIP stockholders may change if Diffusion's net cash is between \$12.0 million and \$16.0 million at the closing of the Merger and holding all other assumptions related to the calculation of the Exchange Ratio described elsewhere in this proxy statement/prospectus/information statement the same. The estimates of the Exchange Ratio and the parties' respective ownership of shares of the combined company outstanding immediately after the Effective Time in the table below are calculated based upon (i) the parties' respective capitalizations as of the date of the Merger Agreement, (ii) the closing price of the Diffusion Common Stock on the preceding day, and (iii) an assumed conversion price of the EIP Convertible Notes of \$3.00.

Diffusion Net Cash at Closing (\$ in millions)	Exchange Ratio	Post-Merger Ownership	
		Diffusion Equity Holders	EIP Equity Holders
\$12.0 million	0.1943	21.98%	78.02%
\$12.5 million	0.1915	22.23%	77.77%
\$13.0 million	0.1887	22.49%	77.51%
\$13.5 million	0.1860	22.74%	77.26%
\$14.0 million	0.1860	22.74%	77.26%
\$14.5 million	0.1860	22.74%	77.26%
\$15.0 million	0.1834	22.99%	77.01%
\$15.5 million	0.1809	23.23%	76.77%
\$16.0 million	0.1784	23.48%	76.52%

Calculation of Diffusion Net Cash

The Merger Agreement includes a condition to EIP's obligation to close the Merger that requires Diffusion to have a minimum of \$12.0 million in net cash immediately prior to the closing of the Merger (as calculated pursuant to the terms of the Merger Agreement).

On or prior to the date that is ten (10) days prior to the anticipated closing date of the Merger, Diffusion will deliver to EIP a written schedule prepared in accordance with the Merger Agreement and certified by the Chief Financial Officer of Diffusion, setting forth, in reasonable detail, Diffusion's good faith estimate of Diffusion's net cash as of the anticipated closing date of the Merger. The anticipated closing date will be a date that Diffusion and EIP mutually agree in good faith. Upon the reasonable request of EIP, Diffusion will make the work papers and back-up materials used or useful in preparing the net cash schedule available to EIP and, as reasonably requested by EIP, Diffusion's accountants and counsel at reasonable times and upon reasonable notice. EIP will have the right to dispute any part of such schedule by delivering a written notice to that effect to Diffusion.

Under the Merger Agreement, "net cash" means:

- Diffusion's and its subsidiaries' cash and cash equivalents as of the anticipated closing date, determined in a manner consistent with the manner in which such items were determined in the audited consolidated balance sheets of Diffusion and its subsidiaries as of December 31, 2020, December 31, 2021 and December 31, 2022 and the related audited consolidated statements of operation, comprehensive loss, members' equity and cash flows for the fiscal year or relevant period ended December 31, 2020, December 31, 2021 and December 31, 2022, respectively, together with all of the related notes and schedules thereto, accompanied by the reports thereon of Diffusion's independent auditors (the "Diffusion Audited Financial Statements"), *minus* the sum, without duplication of:
 - o Diffusion's and its subsidiaries' accounts payable and accrued expenses (including accrued tax liabilities, Diffusion's expenses arising out of the Merger and the transactions contemplated under the Merger Agreement, unpaid fees and expenses incurred with respect to Diffusion's audit of its consolidated financial statements for the fiscal year ended December 31, 2022 and actual unpaid wind-down costs associated with discontinued clinical trials and lab, R&D and related operations, if any); and

- o Diffusion's and its subsidiaries' other current liabilities payable in cash,

in each case as of the anticipated closing date and determined in a manner consistent with the manner in which such items were determined in the Diffusion Audited Financial Statements (except to the extent such amounts are non-cash liabilities with respect to individuals offered employment as continuing employees following the Merger or who will otherwise be continuing to provide services to Diffusion or any of its subsidiaries following the Effective Time)

In addition, under the Merger Agreement, net cash will be increased by an amount equal to the sum of (without duplication): (1) Diffusion's and its subsidiaries' accounts receivable, deposits and prepaid expenses (including prepaid premiums for directors' and officers' insurance, if any, or any credit due to Diffusion or any of its subsidiaries arising from the early termination of Diffusion's existing insurance policies the value of which is reasonably expected to be realized by the surviving company) and the pre-paid public company expenses listed or described in the disclosure schedules), (2) any out of pocket fees and expenses incurred by Diffusion or any of its subsidiaries after the date of the Merger Agreement and prior to the Effective Time in connection with actions taken at the written request of EIP other than pursuant to, and in accordance with, the Merger Agreement, (3) any out of pocket fees and expenses, if any, incurred by Diffusion or any of its subsidiaries to the extent EIP requests Diffusion add EIP and its subsidiaries as additional insureds to any director's and officers' liability insurance tail policy as Diffusion's successor in interest, (4) 50% of the aggregate amount of all fees and expenses incurred by Diffusion and its subsidiaries in connection with the filing and mailing, as applicable, of this proxy statement/prospectus/information statement, (5) 50% of any Diffusion stockholder litigation costs, (6) any cash proceeds from a disposition of TSC that are not distributed to the stockholders of Diffusion prior to the Effective Time, and (7) 50% of the aggregate amount of all fees and expenses incurred by Diffusion and its subsidiaries in connection with the listing of shares of Diffusion Common Stock with Nasdaq.

Diffusion's net cash balance at the anticipated closing date is subject to numerous factors. If Diffusion's net cash immediately prior to the Closing is less than \$12.0 million, based on the manner of calculating net cash pursuant to the Merger Agreement, Diffusion would be unable to satisfy a closing condition for the Merger, in which case EIP could elect to waive the condition or choose to not consummate the Merger. Furthermore, the Exchange Ratio at the Closing will be subject to adjustment to the extent that Diffusion's net cash immediately prior to the Closing is less than \$13.5 million or greater than \$14.5 million, as described under "*The Merger Agreement—Merger Consideration and Exchange Ratio—Exchange Ratio*" beginning on page 146.

Treatment of EIP Stock Options and Warrants

For a description of the treatment of EIP's stock options and warrants under the Merger Agreement see the sections titled "*The Merger — Treatment of EIP Stock Options*" and "*The Merger — Treatment of EIP Warrants*" beginning on page 137.

Directors and Executive Officers of the Combined Company Following the Merger

Pursuant to the Merger Agreement, the directors of EIP and Diffusion who will not serve as directors following the Effective Time will resign at or prior to the Effective Time. Effective as of the Effective Time, the combined company's board of directors will be fixed at seven members, five of whom will be directors designated by EIP and two of whom will be directors designated by Diffusion. It is anticipated that the executive officers of the combined company will be a combination of Diffusion's and EIP's current executive officers. See section titled "*Management Following the Merger — Executive Officers and Directors of the Combined Company Following the Merger*" beginning on page 247.

Conditions to the Closing of the Merger

The following contains a description of all material conditions to the closing of the Merger.

Each party's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the closing of the Merger, of various conditions, which include, in addition to other customary closing conditions, the following:

- the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, shall have been declared effective by the SEC in accordance with the Securities Act and shall not be subject to any stop order or proceeding, or any proceeding threatened by the SEC, seeking a stop order;
- (1) the existing shares of Diffusion Common Stock shall have been continually listed on Nasdaq as of and from the date of the Merger Agreement through the closing date of the Merger, (2) the shares of Diffusion Common Stock to be issued in the Merger pursuant to the Merger Agreement shall have been approved for listing, subject to official notice of issuance, on Nasdaq after the closing, and (3) to the extent required by Nasdaq Marketplace Rule 5110, the initial listing application for the Diffusion Common Stock on Nasdaq has been approved for listing (subject to official notice of issuance);
- there shall not have been issued any order preventing the closing of the Merger and no law making the closing of the Merger illegal;
- the holders of EIP capital stock shall have adopted and approved the Merger Agreement, the Merger and the transactions contemplated by the Merger Agreement by the requisite vote in accordance with EIP's organizational documents and the Delaware General Corporation Law; and
- the holders of Diffusion Common Stock shall have approved issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement and, if applicable, the Reverse Split by the requisite vote in accordance with EIP's organizational documents and the Delaware General Corporation Law.

In addition, the obligation of Diffusion and Merger Sub to complete the Merger is further subject to the satisfaction or waiver of the following conditions:

- certain fundamental representations and warranties of EIP shall have been true and correct in all respects as of the date of the Merger Agreement and shall be true and correct in all respects as of the closing date of the Merger with the same force and effect as if made on and as of the date on which the Merger is to be completed or, if such representations and warranties address matters as of a particular date, then such fundamental representations and warranties shall be so true and correct as of that particular date;
- all other representations and warranties of EIP in the Merger Agreement shall have been true and correct as of the date of the Merger Agreement and shall be true and correct on the closing date of the Merger with the same force and effect as if made on the date on which the Merger is to be completed or, if such representations and warranties address matters as of a particular date, then such representations and warranties shall be true and correct as of that particular date, except where the failure of these representations and warranties to be true and correct, individually or in the aggregate, would not reasonably be expected to have a material adverse effect on EIP;
- EIP shall have performed or complied with in all material respects all of its covenants and agreements in the Merger Agreement required to be performed or complied with by it on or before the closing of the Merger;
- EIP shall have delivered certain certificates and other documents required under the Merger Agreement for the closing of the Merger;
- all stockholders' agreements, voting agreement, registration rights agreement, co-sale agreement or any other similar contract between EIP and any holders of EIP's stock, including any contract granting any person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights, shall have been terminated;
- the lock-up agreements executed concurrently with the Merger by the directors, executive officers and certain affiliates of EIP continue to be in full force and effect;

- since the date of the Merger Agreement, there shall have been no event, change, circumstance, occurrence, effect or state of facts that (1) is or would reasonably be expected to be, individually or in the aggregate, materially adverse to the business, condition (financial or otherwise), assets, liabilities, or results of operations of EIP and its subsidiaries, taken as a whole or (2) materially impairs the ability of EIP to consummate the Merger or any of the other transactions contemplated by the Merger Agreement; provided, that the Merger Agreement provides that certain effects, changes, events, circumstances, or developments arising or resulting from the following shall not be considered a material adverse effect on EIP:
 - o general economic or business conditions affecting the industry in which EIP and its subsidiaries operate;
 - o acts of war, armed hostilities or terrorism;
 - o epidemics, pandemics or disease outbreaks (including the COVID-19 virus) or any worsening of such epidemic, pandemic or disease outbreak or any declaration of martial law, quarantine or similar directive, policy or guidance or law or other action by any governmental entity in response thereto;
 - o changes in financial, banking or securities markets;
 - o the taking of any action required to be taken under the Merger Agreement;
 - o any failure, in and of itself, by EIP to meet any internal or published projections, forecasts, estimates, or predictions in respect of revenues, earnings, or other financial or operating metrics for any period (it being understood that the facts or occurrences giving rise to or contributing to such failure may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a EIP material adverse effect, to the extent permitted by this definition and not otherwise excepted by a clause of this proviso);
 - o any specific action taken (or omitted to be taken) by EIP or any of its subsidiaries at or with the express written direction or written consent of Diffusion (other than any such action or omission required by the Merger Agreement);
 - o any change in or any compliance with or action taken for the purpose of complying with any law or GAAP; or
 - o the announcement of the Merger Agreement or pendency of the Merger.
- The conversion of EIP Preferred Stock and EIP Convertible Notes shall have been completed in accordance with the Merger Agreement and no shares of EIP Preferred Stock or EIP Convertible Notes shall be outstanding.
- EIP shall have delivered to Diffusion evidence reasonably satisfactory to Diffusion that EIP's funding mechanism awarded from the NIA.

In addition, the obligation of EIP to complete the Merger is further subject to the satisfaction or waiver of the following conditions:

- certain fundamental representations and warranties of Diffusion shall have been true and correct in all respects on the date of the Merger Agreement and shall be true and correct in all respects on the closing date of the Merger with the same force and effect as if made on and as of the date on which the Merger is to be completed or, if such representations and warranties address matters as of a particular date, then such fundamental representations and warranties shall be so true and correct as of that particular date;
- all other representations and warranties of Diffusion in the Merger Agreement shall have been true and correct as of the date of the Merger Agreement and shall be true and correct on the closing date of the Merger with the same force and effect as if made on the date on which the merger is to be completed or, if such representations and warranties address matters as of a particular date, then such representations and warranties shall be true and correct as of that particular date, except where the failure of these representations and warranties to be true and correct, individually or in the aggregate, would not reasonably be expected to have a material adverse effect on Diffusion;
- Diffusion and Merger Sub shall have performed or complied with in all material respects all of their covenants and agreements in the Merger Agreement required to be performed or complied with by it on or before the Effective Time;

- Diffusion shall have delivered certain certificates and other documents required under the Merger Agreement for the closing of the Merger;
- Diffusion shall have a minimum of \$12.0 million of Diffusion's net cash as calculated under the Merger Agreement;
- Diffusion shall have caused Diffusion's board of directors to be constituted as set forth in the Merger Agreement, effective as of the Effective Time;
- the lock-up agreements executed concurrently with the Merger by the directors and executive officers of Diffusion continue to be in full force and effect;
- Diffusion shall have delivered to EIP written resignations of the officers and directors of Diffusion and any of its subsidiaries who are not to continue as officers or directors of Diffusion or any of its subsidiaries pursuant to the terms of the Merger Agreement, in a form satisfactory to EIP;
- since the date of the Merger Agreement, there shall have been no event, change, circumstance, occurrence, effect or state of facts that (A) is or would reasonably be expected to be, individually or in the aggregate, materially adverse to the business, condition (financial or otherwise), assets, liabilities, or results of operations of Diffusion and its subsidiaries, taken as a whole or (B) materially impairs the ability of the Diffusion to consummate the merger or any of the other transactions contemplated by the Merger Agreement; provided, that the Merger Agreement provides that certain effects, changes, events, circumstances, or developments arising or resulting from the following shall not be considered a material adverse effect on Diffusion:
 - o general economic or business conditions affecting the industry in which Diffusion and its subsidiaries operate;
 - o acts of war, armed hostilities or terrorism;
 - o epidemics, pandemics or disease outbreaks (including the COVID-19 virus) or any worsening of such epidemic, pandemic or disease outbreak or any declaration of martial law, quarantine or similar directive, policy or guidance or law or other action by any governmental entity in response thereto;
 - o changes in financial, banking or securities markets;
 - o the taking of any action required to be taken under the Merger Agreement;
 - o any failure, in and of itself, by Diffusion to meet any internal or published projections, forecasts, estimates, or predictions in respect of revenues, earnings, or other financial or operating metrics for any period (it being understood that the facts or occurrences giving rise to or contributing to such failure may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Diffusion material adverse effect);
 - o any change, in and of itself, in the market price or trading volume of Diffusion's securities or in its credit ratings (it being understood that the facts or occurrences giving rise to or contributing to such change may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Diffusion material adverse effect);
 - o any specific action taken (or omitted to be taken) by Diffusion or any of its subsidiaries at or with the express written direction or written consent of Diffusion (other than any such action or omission required by the Merger Agreement);
 - o any change in or any compliance with or action taken for the purpose of complying with any law or GAAP; or
 - o the announcement of the Merger Agreement or pendency of the merger; and
- Neither the principal executive officer nor the principal financial officer of Diffusion shall have failed to provide, with respect to any Diffusion document filed (or required to be filed) with the SEC on or after the date of the Merger Agreement, any required certification in the form required under Rule 13a-14 promulgated under the Exchange Act and 18 U.S.C. section 1350.

- Notwithstanding the foregoing, certain closing conditions may not be waived due to applicable law or otherwise. The following closing conditions may not be waived: receipt of the requisite stockholder approvals by each party; the effectiveness of the registration statement of which this proxy statement/prospectus/information statement forms a part; and the absence of any order or injunction that has the effect of prohibiting the consummation of the Merger. The foregoing closing conditions are the only closing conditions to the Merger that may not be waived. All other closing conditions to the Merger may be waived by EIP and/or Diffusion, as applicable.

Representations and Warranties

The Merger Agreement contains customary representations and warranties of Diffusion, Merger Sub, and EIP for a transaction of this type relating to, among other things:

- corporate organization, organizational and governing documents, and power, and similar corporate matters;
- subsidiaries;
- capitalization;
- financial statements;
- absence of certain changes or events;
- title to assets;
- real property and leaseholds;
- intellectual property;
- the validity of material contracts to which the parties or their subsidiaries are a party and any violation, default or breach under such contracts;
- non-contravention and required consents;
- absence of undisclosed liabilities;
- regulatory compliance, permits and restrictions;
- tax matters;
- employee and labor matters and benefit plans;
- environmental matters;
- insurance;
- legal proceedings and orders;
- authority to enter into the Merger Agreement and the related agreements;
- compliance with anti-bribery laws;
- full disclosure;
- governmental authorization;
- transactions with affiliates;
- votes required for the closing of the Merger and approval of the proposals that will come before the Diffusion special meeting and that will be the subject of EIP stockholder approval;
- any brokerage or finder's fee or other fee or commission in connection with the Merger;
- information technology and data privacy
- with respect to Diffusion, opinion of its financial advisor;
- with respect to Diffusion, the valid issuance in the Merger of the Diffusion Common Stock;

- with respect to Diffusion, contract termination fees and severance payments; and
- with respect to EIP, accuracy of the information supplied by EIP for inclusion in this registration statement/proxy statement/information statement.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the Merger, but their accuracy forms the basis of some of the conditions to the obligations of EIP and Diffusion to complete the Merger.

Non-Solicitation

Each of Diffusion and EIP agreed that during the period commencing on the date of the Merger Agreement and ending on the earlier of the consummation of the Merger or the termination of the Merger Agreement, except as described below, Diffusion and EIP will not, nor will either party authorize any of the directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors or representatives retained by it to, directly or indirectly:

- solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any “acquisition proposal” or “acquisition inquiry” (each as defined below) or take any action that could reasonably be expected to lead to an acquisition proposal or acquisition inquiry;
- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or acquisition inquiry;
- engage in discussions or negotiations with any third person with respect to any acquisition proposal or acquisition inquiry;
- approve, endorse or recommend an acquisition proposal; or
- waive, terminate, modify or fail to enforce any provision of any “standstill” or similar obligation of any third person with respect to the it or any of its subsidiaries; or
- execute or enter into any letter of intent or similar document or any contract providing for any acquisition proposal.

An “acquisition inquiry” means any existing solicitations, discussions or negotiations with any third persons that may be ongoing with respect to any inquiry, proposal, discussion, offer or request that constitutes or would reasonably be expected to lead to an acquisition proposal.

An “acquisition proposal” means any proposal or offer from a third person with respect to any direct or indirect acquisition or purchase or license, in one transaction or a series of transactions, and whether through any merger, reorganization, consolidation, contribution, tender offer, exchange offer, stock acquisition, asset acquisition, binding share exchange, business combination, recapitalization, liquidation, dissolution, joint venture, licensing, sale-leaseback or similar transaction, or otherwise, (A) of assets or businesses of Diffusion or EIP, as applicable, and their respective subsidiaries that generate 20% or more of the consolidated net revenues or net income (for the twelve month period ending on the last day of Diffusion’s or EIP’s, as applicable, most recently completed fiscal quarter) or that represent 20% or more of the total assets (based on fair market value) of Diffusion or EIP, as applicable, and their respective subsidiaries, taken as a whole, immediately prior to such transaction (in each case other than with respect to a permitted asset disposition as defined in the Merger Agreement in the case of an acquisition proposal), (B) of 20% or more of any class of capital stock, other equity securities or voting power of Diffusion or EIP, as applicable, and their respective subsidiaries or any resulting parent company of Diffusion or EIP, as applicable, in each case other than the merger and other transactions contemplated by the Merger Agreement, or (C) pursuant to which the stockholders of Diffusion or EIP, as applicable, immediately prior to the consummation of such transaction hold less than 80% of the equity interests of the surviving or resulting entity of such transaction.

Before obtaining the applicable Diffusion stockholder approvals required to consummate the merger, Diffusion may furnish nonpublic information regarding Diffusion and its subsidiaries to, and may enter into discussions or negotiations with, any person in response to a bona fide written acquisition proposal made or received after the date of the Merger Agreement, which Diffusion's board of directors determines in good faith, after consultation with Diffusion's outside financial advisors and outside legal counsel, constitutes or is reasonably likely to result in a "superior proposal," as defined below, and is not withdrawn, if:

- neither Diffusion nor any of Diffusion's representatives has breached the non-solicitation provisions of the Merger Agreement described above;
- Diffusion's board of directors concludes in good faith, based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of such board of directors under applicable law;
- Diffusion receives from the third-party an executed confidentiality agreement containing provisions at least as favorable to Diffusion as those contained in the confidentiality agreement between Diffusion and EIP; and
- At least two business days prior to furnishing of any such nonpublic information to, or entering into discussions with, a person, Diffusion gives EIP written notice of the identity of such person and of Diffusion's intention to furnish nonpublic information to, or enter into discussions with, such person and furnishes the same non-public information to EIP.

Neither Diffusion's board of directors nor any committee thereof may make a Parent Adverse Recommendation Change (as defined in section titled "*Termination of the Merger Agreement*" below). Notwithstanding the foregoing, Diffusion's board of directors may make a Parent Adverse Recommendation Change and, with respect to a superior proposal, terminate the Merger Agreement to accept a superior proposal if, prior to receipt of the approval by the Diffusion stockholders:

- Diffusion has received a superior proposal or an intervening event has occurred;
- Diffusion's board of directors has determined in good faith, after consultation with outside counsel, that the withdrawal or modification of its approval or recommendation of the Merger Agreement or the Merger is required for the purpose of fulfilling its fiduciary duties, and Diffusion has notified EIP in writing of this determination; and
- at least four business days following receipt by EIP of this notice, and taking into account any revised proposal made by EIP since receipt of this notice, Diffusion's board of directors determines that the failure to make such change in recommendation would be inconsistent with its fiduciary duties to Diffusion's stockholders under applicable law.

"Superior proposal" means any unsolicited bona fide written acquisition proposal, that: (i) did not result from a breach of the Merger Agreement and (ii) Diffusion's board of directors determines in good faith (after consultation with outside counsel and its financial advisor) based on such matters that it deems relevant (including the likelihood of consummation thereof and the financing terms thereof), is more favorable to the stockholders of Diffusion (in their capacity as such) from a financial point of view than the Merger (including any adjustment to the terms and conditions proposed by EIP in writing in response to such acquisition proposal in accordance with the Merger Agreement); provided, that, for purposes of this definition of "Superior Proposal," all references to "20% or more" shall be deemed to be references to "50% or more" and all references to "less than 80%" shall be deemed to be references to "less than 50%."

An "intervening event" means a material fact, event, change, development or circumstance that was not known or reasonably foreseeable to Diffusion's board of directors prior to Diffusion's execution of the Merger Agreement, which fact, event, change, development or circumstance, or any material consequence thereof, becomes known to Diffusion's board of directors after the date of this Agreement and prior to the receipt of the requisite approval of Diffusion's stockholders in connection with the Merger Agreement, which fact, event, change, development or circumstance is material to Diffusion and does not relate to (A) an acquisition proposal, inquiry or the consequences thereof, (B) the announcement, pendency or consummation of the Merger or any actions required to be taken pursuant to the Merger Agreement, (C) the fact, in and of itself, that Diffusion meets or exceeds internal budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations, or (D) any change in the price of Diffusion Common Stock (it being acknowledged that any underlying cause of any change in the price of Diffusion Common Stock may be taken into account for purposes of determining whether an intervening event has occurred for purposes of this clause (D)).

Nothing in the Merger Agreement prohibits Diffusion from taking and disclosing to its stockholders a position contemplated by Rules 14d-9 or 14e-2(a), promulgated under the Exchange Act regarding an acquisition proposal.

Meetings of Stockholders

Diffusion is obligated under the Merger Agreement to use commercially reasonable efforts to take all action necessary to call, give notice of and hold a meeting of its stockholders for the purposes of voting on the issuance of shares of Diffusion Common Stock in the Merger and the Reverse Split.

EIP is obligated under the Merger Agreement to obtain written consents of its stockholders sufficient to adopt the Merger Agreement and approve the Merger and the other transactions contemplated thereby reasonably promptly, and no later than one business day following this registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC. EIP's board of director's recommendation that EIP stockholders approve the Merger Agreement and the transactions contemplated thereby shall not be withdrawn or modified (and EIP's board of directors shall not publicly propose to withdraw or modify such recommendation) in a manner adverse to Diffusion, and no resolution by EIP's board of directors or any committee thereof to withdraw or EIP's board of directors in a manner adverse to Diffusion or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any alternative acquisition proposal shall be adopted or proposed.

Covenants; Conduct of Business Pending the Merger

Diffusion has agreed that, except as permitted by the Merger Agreement, as required by law, or unless EIP shall have provided written consent, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the Merger and the termination of the Merger Agreement, Diffusion will conduct its business and operations in the ordinary course consistent with past practices and in compliance with all applicable laws, regulations and certain contracts. Diffusion has also agreed that, subject to certain limited exceptions, without the consent of EIP, it will not, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement:

- (A) declare, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock, except for dividends by a wholly owned subsidiary of Diffusion, as applicable, to its parent; (B) purchase, redeem or otherwise acquire any shares of capital stock or other securities (except for the withholding of shares of Diffusion Common Stock in satisfaction of the applicable exercise price and/or withholding taxes upon the settlement of Diffusion restricted stock units or exercise of Diffusion options or warrants); or (C) split, combine, reclassify or otherwise amend the terms of any of the shares of capital stock or other equity interests of Diffusion (other than the repurchase of shares from terminated employees, directors or consultants or the issuance of shares issued upon the exercise of exercise of Diffusion options or warrants (to the extent issued in accordance with their terms as in effect on March 29, 2023));
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: any capital stock or other security (except for Diffusion Common Stock issued upon the valid exercise or settlement of outstanding options or restricted stock units to purchase shares of Diffusion Common Stock); any option, warrant or right to acquire any capital stock or any other security of Diffusion; or any instrument convertible into or exchangeable for any capital stock or other security of Diffusion (except for Diffusion Common Stock issued in connection with any equity financing the proceeds of which will be used to increase the Diffusion Net Cash in excess of \$12.0 million);
- except as required to give effect to anything in contemplation of the closing of the Merger (including the Diffusion Reverse Split, if any), amend the certificate of incorporation, as amended, bylaws, as amended, or other charter or organizational documents of Diffusion, or effect or become a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;

- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into any joint venture with any other entity;
- directly or indirectly sell, lease, license, sell and leaseback, abandon, mortgage or otherwise encumber or subject to any lien (other than any lien permitted under the Merger Agreement) or otherwise dispose in whole or in part of any of its material properties, assets or rights or any interest therein (including any Diffusion owned intellectual property), except (i) any permitted asset disposition and (ii) the granting of non-exclusive licenses of intellectual property in the ordinary course of business consistent with past practice, the abandonment of intellectual property in the exercise of the good faith business judgment of Diffusion and the expiration of intellectual property in accordance with the applicable statutory term to the extent not extendable;
- adopt or enter into a plan of complete or partial liquidation, dissolution, restructuring, recapitalization or other reorganization;
- (A) incur, create, assume or otherwise become liable for, or repay or prepay, any indebtedness for borrowed money, or amend, modify or refinance any Indebtedness of borrowed money, or (B) make any loans, advances or capital contributions to, or investments in, any other person, other than Diffusion or any direct or indirect wholly owned subsidiary of Diffusion;
- incur or commit to incur any capital expenditure or authorization or commitment with respect thereto that in the aggregate are in excess of \$100,000;
- (A) pay, discharge, settle or satisfy any claims, liabilities or obligations (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than the payment, discharge or satisfaction in the ordinary course of business consistent with past practice or as required by their terms as in effect on the date of the Merger Agreement of claims, liabilities or obligations reflected or reserved against in certain documents filed by Diffusion with the SEC or incurred since the date of such financial statements in the ordinary course of business consistent with past practice, (B) cancel any material indebtedness owed to Diffusion or any of its subsidiaries, or (C) waive, release, grant or transfer any right of material value, in each case other than any permitted asset disposition;
- (A) materially modify, materially amend, terminate, cancel or extend any material contract or (B) other than in the ordinary course of business consistent with past practice, enter into any material contract (other than a contract relating to the disposition of Diffusion's product candidates, trans sodium crocetin and DFN-529);
- except with respect to any action to enforce Diffusion's rights under the Merger Agreement, commence any action (other than an action as a result of an action commenced against Diffusion or any of its subsidiaries), or compromise, settle or agree to settle any action (including any action relating to the Merger Agreement or the transactions contemplated by the Merger Agreement) other than compromises, settlements or agreements in the ordinary course of business consistent with past practice that involve only the payment of money damages not in excess of \$50,000 individually or \$100,000 in the aggregate, in any case without the imposition of any equitable relief on, or the admission of wrongdoing by, Diffusion or any of its subsidiaries; provided, however, that this shall not apply to any action the defense of which is under the control of any insurer of Diffusion or any of its subsidiaries;
- change Diffusion's financial or tax accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or applicable law, or revalue any of its material assets;
- make any change in Diffusion's policies or any of its subsidiaries as in effect on the date of the Merger Agreement with respect to cash management practices, including the payment of accounts payable or accrued expenses or the collection of accounts receivable or other receivables, or otherwise make any change with respect to the management of working capital;
- settle or compromise any material tax liability; file any amended tax return or surrender any claim for a tax refund; make, revoke or modify any entity classification or other material tax election; file any tax return other than on a basis consistent with past practice; consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of taxes; grant any power of attorney with respect to taxes; or enter into any tax allocation agreement, tax sharing agreement, tax indemnity agreement, tax holiday or any closing or other similar agreement (other than an agreement entered into in the ordinary course of business, the primary purpose of which is not related to taxes), or change any method of accounting for tax purposes;

- change Diffusion's fiscal year;
- except as required by the terms of any Diffusion employee benefit plan as in effect immediately prior to the date of the Merger Agreement, as required by applicable law or as required to maintain the tax qualified status of any such plan, (A) grant any director, officer, employee or consultant any increase in base salary or hourly wage rate, bonus opportunity or other material benefits (other than base salary (and corresponding annual bonus opportunity) increases made in the ordinary course of business consistent with past practice for employees whose annual base salary immediately prior to such increase does not exceed \$75,000), or pay any bonus of any kind to any current or former director, officer, employee or consultant, (B) grant or pay to any current or former director, officer, employee or consultant any severance, change in control or termination pay, or make any modifications thereto or increases therein (other than as the automatic and non-discretionary result of a permitted base salary or annual bonus opportunity increase under the immediately preceding clause (A)), (C) grant or amend any award of stock options, stock appreciation rights, performance units, restricted stock, restricted stock units or other equity-based or equity-related awards, or remove or modify any restrictions in the Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended, or awards made thereunder, (D) adopt or enter into any collective bargaining agreement or other labor union contract, (E) take any action to accelerate the vesting, funding or payment of any compensation or benefit under any Diffusion employee benefit plan or (F) adopt, enter into or establish any new Diffusion employee benefit plan or materially amend, modify or terminate any existing Diffusion employee benefit plan.
- (A) hire any employee at the executive level or higher or (B) other than in the ordinary course of business consistent with past practice, hire any other employee;
- terminate (or provide notice of termination to) any executive officer of Diffusion with an annual base salary in excess of \$150,000 or otherwise request that any such executive officer resign, in each case other than for cause or poor performance (consistent with Diffusion's past practices);
- fail to keep in force any material insurance policies or replace or revise provisions regarding insurance coverage in any material respect, in each case with respect to the assets, operations and activities of Diffusion and its subsidiaries as currently in effect;
- renew or enter into any non-compete, exclusivity, non-solicitation or similar agreement that would restrict or limit, in any material respect, the operations of Diffusion or any of its subsidiaries (other than any exclusivity for a permitted asset disposition);
- participate in any inspections, scheduled meetings or teleconferences with, or correspond in writing, communicate or consult with the FDA without providing EIP (whenever feasible and to the extent permitted under applicable law) with prior written notice and, within 24 hours from the time such written notice is delivered, the opportunity to consult with Diffusion with respect to such inspection, correspondence, communication or consultation;
- commence any new preclinical or clinical trial not initiated as of the date of the Merger Agreement, or enter into any new line of business outside of its existing business;
- enter into any new real property lease or amend the terms of any existing real property lease;
- after the Diffusion's net cash calculation is finalized pursuant to the Merger Agreement, incur any cash expense other than in the ordinary course of business consistent with past practices or in connection with the transactions contemplated by the Merger Agreement; or
- authorize any of, or commit or agree to take any of, the foregoing actions.

EIP has agreed that, except as permitted by the Merger Agreement, as required by law, or unless Diffusion shall have provided written consent, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the Merger and the termination of the Merger Agreement, EIP will conduct its business and operations in the ordinary course consistent with past practices and in compliance with all applicable laws, regulations and certain contracts. EIP has also agreed that, subject to certain limited exceptions, without the consent of Diffusion, it will not, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the Merger and the termination of the Merger Agreement:

- (A) declare, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock of EIP; (B) purchase, redeem or otherwise acquire any shares of capital stock or other securities of EIP (except for withholding taxes upon exercise of EIP options or EIP warrants, in each case outstanding as of the close of business on March 29 2023 (to the extent issued in accordance with their terms as in effect on March 29 2023)); or (C) split, combine, reclassify or otherwise amend the terms of any of the shares of capital stock or other equity interests of EIP (other than the repurchase of shares from terminated employees, directors or consultants or the issuance of shares issued upon the exercise of exercise of EIP options or warrants (to the extent issued in accordance with their terms as in effect on March 29, 2023));
- sell, issue, grant, pledge or otherwise dispose of or encumber (other than with respect to permitted liens under the Merger Agreement) or authorize any of the foregoing with respect to: any capital stock or other security (except for EIP Common Stock issued upon the valid exercise or settlement of outstanding options or restricted stock units to purchase shares of EIP Common Stock); any option, warrant or right to acquire any capital stock or any other security of EIP; or any instrument convertible into or exchangeable for any capital stock or other security of EIP;
- except as required to give effect to anything in contemplation of the closing of the merger, amend the certificate of incorporation, bylaws or other charter or organizational documents of EIP, or effect or become a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into any joint venture with any other entity;
- directly or indirectly sell, lease, license, sell and leaseback, abandon, mortgage or otherwise encumber or subject to any lien (other than any liens permitted under the Merger Agreement) or otherwise dispose in whole or in part of any of its material properties, assets or rights or any interest therein (including any EIP owned intellectual property), except the granting of non-exclusive licenses of intellectual property in the ordinary course of business consistent with past practice, the abandonment of intellectual property in the exercise of the good faith business judgment of EIP, and the expiration of intellectual property in accordance with the applicable statutory term to the extent not extendable;
- adopt or enter into a plan of complete or partial liquidation, dissolution, restructuring, recapitalization or other reorganization;
- (A) incur, create, assume or otherwise become liable for, or repay or prepay, any indebtedness for borrowed money, or amend, modify or refinance any indebtedness of borrowed money, or (B) make any loans, advances or capital contributions to, or investments in, any other person, other than EIP or any direct or indirect wholly owned subsidiary of EIP;
- incur or commit to incur any capital expenditure or authorization or commitment with respect thereto that in the aggregate are in excess of \$100,000;
- (A) pay, discharge, settle or satisfy any claims, liabilities or obligations (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than the payment, discharge or satisfaction in the ordinary course of business consistent with past practice or as required by the their terms in effect on the date of the Merger Agreement of claims, liabilities or obligations incurred since the date of the financial statements in the ordinary course of business consistent with past practice, (B) cancel any material Indebtedness owed to EIP or any of its subsidiaries or (C) waive, release, grant or transfer any right of material value;
- (A) materially modify, materially amend, terminate, cancel or extend any material contract or (B) other than in the ordinary course of business consistent with past practice, enter into any material contract;

- except with respect to any action to enforce EIP's rights under the Merger Agreement, commence any action, compromise, settle or agree to settle any action (including any action relating to the Merger Agreement or the transactions contemplated by the Merger Agreement) other than compromises, settlements or agreements in the ordinary course of business consistent with past practice that involve only the payment of money damages not in excess of \$50,000 individually or \$100,000 in the aggregate, in any case without the imposition of any equitable relief on, or the admission of wrongdoing by, EIP or any of its subsidiaries; provided, however, that this clause (xi) shall not apply to any action the defense of which is under the control of any insurer of EIP or any of its subsidiaries;
- change EIP's financial or tax accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or applicable law, or revalue any of its material assets;
- make any change in the EIP's policies or any of its subsidiaries as in effect on the date of the Merger Agreement with respect to cash management practices, including the payment of accounts payable or accrued expenses or the collection of accounts receivable or other receivables, or otherwise make any change with respect to the management of working capital;
- settle or compromise any material tax liability; file any amended tax return or surrender any claim for a tax refund; make, revoke or modify any entity classification or other material tax election; file any tax return other than on a basis consistent with past practice; consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of taxes; grant any power of attorney with respect to taxes; or enter into any tax allocation agreement, tax sharing agreement, tax indemnity agreement, tax holiday or any closing or other similar agreement (other than an agreement entered into in the ordinary course of business, the primary purpose of which is not related to taxes), or change any method of accounting for tax purposes;
- change EIP's fiscal year;
- except as required by the terms of any EIP employee benefit plan as in effect immediately prior to the date of this Agreement, as required by applicable law or as required to maintain the Tax qualified status of any EIP employee benefit plan, (A) grant any current or former director, officer, employee or other individual service provider of EIP or any of its subsidiaries any increase in base salary or hourly wage rate, bonus opportunity or other material benefits (other than base salary (and corresponding annual bonus opportunity) increases made in the ordinary course of business consistent with past practice for employees whose annual base salary immediately prior to such increase does not exceed \$75,000), or pay any bonus of any kind to any such individual, (B) grant or pay to any such individual any severance, change in control or termination pay, or make any modifications thereto or increases therein, (C) grant or amend any award of stock options, stock appreciation rights, performance units, restricted stock, restricted stock units or other equity or equity-based awards, or remove or modify any restrictions in any EIP equity plan or awards made thereunder, (D) adopt or enter into any collective bargaining agreement or other labor union contract (E) take any action to accelerate the vesting, funding or payment of any compensation or benefit under any EIP employee benefit plan or otherwise, or (F) adopt, enter into or establish any new EIP employee benefit plan or amend, modify or terminate any existing EIP employee benefit plan.
- (A) hire any employee at the executive level or higher or (B) other than in the ordinary course of business consistent with past practice, hire any other employee;
- order or implement any plant closing, mass layoff or other similar action that requires the issuance of notice under the WARN Act or any similar state or local law;
- enter into any collective bargaining agreement or other contract with any union, works council or other labor organization;
- terminate (or provide notice of termination to) any employee of EIP or any of its subsidiaries with an annual base salary in excess of \$150,000 or otherwise request that any such employee of EIP or any of its subsidiaries resign, in each case other than for cause or poor performance (consistent with EIP's past practices);
- fail to keep in force any material insurance policies or replace or revise provisions regarding insurance coverage in any material respect, in each case with respect to the assets, operations and activities of EIP and its subsidiaries as currently in effect;

- renew or enter into any non-compete, exclusivity, non-solicitation or similar agreement that would restrict or limit, in any material respect, the operations of EIP or any of its subsidiaries (including the surviving entity following the merger or any of its subsidiaries);
- participate in any inspections, scheduled meetings or teleconferences with, or correspond in writing, communicate or consult with the FDA without providing Diffusion (whenever feasible and to the extent permitted under applicable law) with prior written notice and, within 24 hours from the time such written notice is delivered, the opportunity to consult with EIP with respect to such inspection, correspondence, communication or consultation;
- commence any new preclinical or clinical trial not initiated as of the date of the Merger Agreement, or enter into any new line of business outside of its existing business;
- enter into any new real property lease or amend the terms of any existing real property lease; or
- authorize any of, or commit or agree to take any of, the foregoing actions.
- Other Agreements
- Each of Diffusion and EIP has agreed to use its commercially reasonable efforts to:
 - satisfy the conditions precedent to the consummation of the transactions contemplated by the Merger Agreement;
 - make all filings and other submissions and give all notices required to be made and given in connection with the Merger;
 - obtain all consents, approvals or waivers reasonably required in connection with the transactions contemplated by the Merger Agreement;
 - lift any injunction prohibiting, or any other legal bar to, the merger or other transactions contemplated by the Merger Agreement.
- Diffusion and EIP have agreed that, among other things:
 - Diffusion shall use commercially reasonable efforts (i) to maintain its existing listing on the Nasdaq Capital Market until the closing of the Merger and to obtain approval of the listing of the combined company on the Nasdaq Capital Market, (ii) prepare and submit a notification form for the listing of the shares of Diffusion Common Stock to be issued in the Merger and cause such shares to be approved for listing (subject to official notice of issuance), (iii) to effect the Reverse Split (to the extent Diffusion and EIP mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq listing application), and (iv) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial listing application for the Diffusion Common Stock on the Nasdaq Capital Market and to cause such Nasdaq listing application to be conditionally approved prior to the Effective Time;
 - for a period of six years after the date on which the Effective Time occurs, Diffusion and EIP as the surviving corporation in the Merger will indemnify each of the directors and officers of Diffusion and EIP to the fullest extent permitted under applicable law; and
 - Diffusion will maintain directors' and officers' liability insurance policies from and after the date on which the Effective Time occurs and will also purchase a six-year prepaid non-cancellable extension of the directors' and officers' liability coverage to the extent required as a result of the termination of coverage under Diffusion's directors' and officers' liability insurance policy in effect prior to the closing of the Merger.

Termination of the Merger Agreement

The Merger Agreement may be terminated at any time before the Effective Time, whether before or after the required stockholder approvals in connection with the transactions have been obtained, as set forth below:

- by mutual written consent of each of Diffusion and EIP;

- by either Diffusion or EIP, if the Merger has not been consummated by August 31, 2023 (the “Outside Date”); provided, that the right to terminate the Merger Agreement pursuant to this provision shall not be available to Diffusion or EIP, as applicable, if such party’s (or, in the case of Diffusion, Merger Sub’s) failure to fulfill in any material respect any of its obligations under the Merger Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated by such date, unless such failure was primarily caused by the other party’s breach of any of its obligations under the Merger Agreement, provided, further, that, in the event that the SEC has not declared the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, effective under the Securities Act by the date which is 30 calendar days prior to such date, then Diffusion or EIP shall be entitled to extend such date for an additional 60 calendar days by written notice to the other party;
- by either Diffusion or EIP if a court of competent jurisdiction or governmental entity has issued a final and non-appealable order, decree or ruling or taken any other action that has the effect of permanently restraining, enjoining or otherwise prohibiting the Merger;
- by Diffusion, if EIP did not obtain the written consent of a requisite stockholders necessary to adopt the Merger Agreement and approve the Merger and related matters within one business day of the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, becoming effective, provided, however, this right to terminate the Merger Agreement will not be available to Diffusion once EIP obtains such approval;
- by Diffusion or EIP if the Diffusion stockholders do not approve the transactions at the Diffusion stockholders’ meeting (including any adjournments and postponements thereof), provided, however, this right to terminate the Merger Agreement will not be available to any party if such party’s action or failure to act has been a principal cause of the failure and such action or failure to act constitutes a breach of the Merger Agreement;
- by EIP, at any time prior to the approval by Diffusion’s stockholders of the issuance of the shares of Diffusion Common Stock pursuant to the Merger, if: (A) a Parent Adverse Recommendation Change (as defined below) shall have occurred, (B) a Parent Triggering Event (as defined below) shall have occurred, or (C) Diffusion or any then director or officer of Diffusion shall have willfully breached the non-solicitation prohibition in the Merger Agreement (each, a “Triggering Event”);
- by Diffusion or EIP if the other party to the Merger Agreement has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of the other party has become inaccurate, in either case such that the conditions to the closing of the Merger would not be satisfied as of time of such breach or inaccuracy, but if such breach or inaccuracy is curable, then the Merger Agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of the earlier of (1) the Outside Date and (2) a ten (10)-day period after delivery of written notice of such breach or inaccuracy and the intention to terminate;
- by EIP, if at any time after the date of the Merger Agreement and prior to the closing of the Merger, Diffusion’s net cash (as calculated in accordance with the Merger Agreement) has fallen below \$12.0 million such that the condition to closing would not be satisfied as of the closing date of the Merger and such deficiency is not reasonably capable of being cured prior to the closing date of the Merger; or
- by Diffusion, prior to receipt of the required stockholder approvals to complete the Merger and, if necessary, consummate the reverse stock split of Diffusion Common Stock, if the Diffusion board of directors authorized Diffusion to enter into an acquisition agreement, merger agreement or similar agreement (other than an acceptable confidentiality agreement) with respect to an acquisition proposal, or an alternative acquisition agreement; provided however, that Diffusion shall not enter into any alternative acquisition agreement unless (i) Diffusion has materially complied with its obligations under the Merger Agreement to enter into an alternative acquisition agreement and (ii) Diffusion concurrently pays to EIP a nonrefundable fee in an amount equal to \$765,000 (the “Company Termination Fee”), as required by the Merger Agreement.

For purposes of this section, “Parent Adverse Recommendation Change” means Diffusion board of directors or a committee thereof: (1) withdrawing (or modifying or qualifying in any manner adverse to EIP) the Diffusion board of directors’ recommendation, (2) within five business days of a tender or exchange offer for shares of Diffusion Common Stock having been commenced that would have the effect of precluding the Merger, failing to publicly recommend against such tender or exchange offer, (3) failing to include in the proxy statement/prospectus/information statement that is mailed to Diffusion’s stockholders the Diffusion board of directors’ recommendation, (4) approving or otherwise declaring advisable, or recommending the approval by the Diffusion stockholders of, any acquisition proposal, (5) other than in the context of a tender or exchange offer for shares of Diffusion Common Stock, failing to publicly reaffirm (if so requested by EIP) the Diffusion board of directors’ recommendation after the date any acquisition proposal or any material modification thereto (which request shall only be made once per acquisition proposal or material modification) is first publicly announced, within five business days after a request to do so by EIP.

For purposes of this section, “Parent Triggering Event” shall be deemed to have occurred if: (i) Diffusion shall have failed to include in this proxy statement/prospectus/information statement the Diffusion board of directors’ recommendation (A) approving the execution, delivery, and performance of the Merger Agreement and the consummation of the transactions contemplated thereby, including the Merger and (B) that the stockholders of Diffusion vote in favor of the matters set forth herein, or if Diffusion shall have made a Parent Adverse Recommendation Change; (ii) the Diffusion board of directors or any committee thereof shall have approved, endorsed or recommended any acquisition proposal; or (iii) Diffusion shall have entered into any letter of intent or similar document or any contract relating to any acquisition proposal (other than a confidentiality agreement permitted pursuant to the terms of the Merger Agreement).

Termination Fees

Company Termination Fee payable by Diffusion

Diffusion must pay EIP the Company Termination Fee, if:

- Any of the following occurs:

(i) the Merger Agreement is terminated by Diffusion, at any time prior to the approval by Diffusion’s stockholders of the issuance of the shares of Diffusion Common Stock pursuant to the Merger, because Diffusion’s board of directors authorized Diffusion to enter into an alternative acquisition agreement;

(ii) the Merger Agreement is terminated by EIP, at any time prior to the approval by Diffusion’s stockholders of the issuance of the shares of Diffusion Common Stock pursuant to the Merger, because Diffusion’s board of directors authorized Diffusion to enter into an alternative acquisition agreement, a Triggering Event occurred, or Diffusion or any of its board of directors had willfully breached the non-solicitation provisions of the Merger Agreement; or

(iii) (A) (1) the Merger Agreement is terminated by Diffusion or EIP in the event the stockholders of Diffusion do not approve the issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement at the Diffusion stockholders’ meeting (including any adjournments and postponements thereof); or

- o (2) the Merger Agreement is terminated by EIP in the event (i) the Merger has not been consummated on or before the Outside Date or (ii) Diffusion has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of Diffusion has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied as of time of such breach or inaccuracy (subject to the cure period described above);

(B) an acquisition proposal with respect to Diffusion has been publicly announced or disclosed or otherwise communicated to Diffusion or the Diffusion board of directors after the date of the Merger Agreement but prior to the termination of the Merger Agreement; and

(C) within 12 months after the date of such termination of the Merger Agreement, Diffusion enters into an alternative acquisition agreement in respect of such acquisition proposal (which is subsequently consummated) or consummates a transaction in respect of the acquisition proposal.

Potential Asset Disposition

Diffusion is entitled, but under no obligation, to sell, transfer, license, assign or otherwise divest TSC and DFN-529 to one or more third parties in one or a series of transactions prior to or substantially concurrently with the Effective Time (the “Asset Dispositions”); provided, that any such Asset Disposition will require, to the extent consistent with applicable laws, the written consent of EIP, not to be unreasonably withheld, conditioned or delayed, if such Asset Disposition would create any post-disposition material liabilities for Diffusion following the Effective Time. If the Asset Dispositions are not completed prior to, concurrently with, or immediately following the Effective Time, TSC and/ or DFN-529 will be retained by Diffusion.

Amendment

The Merger Agreement may be amended with the approval of the respective board of directors of EIP, Merger Sub and Diffusion at any time, except that after the Merger Agreement has been adopted and approved by the stockholders of Diffusion or EIP, no amendment which by law requires further approval by the stockholders of Diffusion or EIP, as the case may be, shall be made without such further approval.

AGREEMENTS RELATED TO THE MERGER

Support Agreements and Written Consent

The directors, executive officers and certain principal stockholders of EIP, in their capacity as stockholders of EIP, are party to a support agreement with Diffusion, pursuant to which, among other things, such stockholders agreed, solely in their capacity as an EIP stockholder, to vote all of their shares of EIP capital stock in favor of the adoption of the Merger Agreement and approval of the Merger and related transactions and to acknowledge that the adoption of the Merger Agreement and approval of the Merger and related transactions is irrevocable. In addition, these EIP stockholders agreed not to, directly or indirectly, knowingly take any action that EIP is not permitted to take under the non-solicitation provisions of the Merger Agreement. The EIP stockholders that are party to a support agreement with Diffusion hold a sufficient number of shares of EIP capital stock to adopt the Merger Agreement and approve the Merger and related transactions. Following the effectiveness of the registration statement of which this proxy statement/prospectus/information statement is a part, such holders will execute written consents to adopt the Merger Agreement and approve the Merger and related transactions.

In addition, the directors and executive officers of Diffusion, in their capacity as Diffusion stockholders, are party to a support agreement with EIP pursuant to which, among other things, such stockholders agreed, solely in their capacity as a stockholder, to vote all of their shares of Diffusion Common Stock in favor of the approval of the issuance of shares of Diffusion Common Stock pursuant to the Merger Agreement. In addition, these Diffusion stockholders agreed not to, directly or indirectly, knowingly take any action that Diffusion is not permitted to take under the non-solicitation provisions of the Merger Agreement. The stockholders of Diffusion that are party to a support agreement with EIP consist of Diffusion's current directors and executive officers who collectively beneficially own or control an aggregate of less than 1% of the outstanding shares of Diffusion Common Stock.

Lock-up Agreements

As a condition to the closing of the Merger, EIP's directors, executive officers and certain principal stockholders, who beneficially hold 69.3% of EIP Common Stock on an as-converted to common stock basis, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company's common stock for up to 180 days following the Effective Time, other than in the case of the lock-up agreements entered into with John Alam, MD, Sylvie Grégoire, PharmD, and the two trusts, of which Michel Grégoire serves as trustee, which will be subject to a 12-month lockup.

In addition, as a condition to the closing of the Merger, Diffusion's directors and executive officers, who beneficially hold less than 1% of outstanding shares of Diffusion Common Stock, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company's common stock for 180 days following the Effective Time.

MATTERS BEING SUBMITTED TO A VOTE OF DIFFUSION STOCKHOLDERS

PROPOSAL NO. 1 (THE STOCK ISSUANCE PROPOSAL):

APPROVAL OF THE ISSUANCE OF COMMON STOCK IN THE MERGER PURSUANT TO NASDAQ LISTING RULES 5635(A) AND 5635(B)

At the Diffusion special meeting, holders of shares of Diffusion Common Stock will be asked to approve, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), (1) the issuance of shares of Diffusion Common Stock pursuant to the Merger, which will represent more than 20% of the shares of Diffusion Common Stock outstanding immediately prior to the Merger and (2) the change of control resulting from the Merger. Under the Exchange Ratio formula described in the Merger Agreement, the equity holders of EIP immediately before the effective time of the Merger are expected to hold approximately 77.26% of the outstanding shares of Diffusion Common Stock immediately after the effective time and the equity holders of Diffusion immediately before the effective time are expected to hold approximately 22.74% of the outstanding shares of Diffusion Common Stock immediately after the effective time, in each case, assuming Diffusion's net cash (as calculated pursuant to the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million.

Required Vote; Recommendation of Board of Directors

Presuming a quorum is present, the affirmative vote of the holders of a majority of the shares of Diffusion Common Stock present in person or represented by proxy at the Diffusion special meeting and entitled to vote generally on the subject matter is required for approval of this proposal.

THE DIFFUSION BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE DIFFUSION STOCKHOLDERS VOTE "FOR" THE STOCK ISSUANCE PROPOSAL TO APPROVE THE ISSUANCE OF SHARES OF DIFFUSION COMMON STOCK PURSUANT TO THE MERGER AGREEMENT.

PROPOSAL NO. 2 (THE REVERSE SPLIT PROPOSAL):

APPROVAL OF AN AMENDMENT TO THE CERTIFICATE OF INCORPORATION, AS AMENDED, OF DIFFUSION TO EFFECT THE REVERSE SPLIT WITHIN A RANGE OF ONE NEW SHARE FOR NOT LESS THAN AND NOT GREATER THAN SHARES OUTSTANDING AT ANY TIME PRIOR TO DECEMBER 31, 2023, THE IMPLEMENTATION AND TIMING OF WHICH SHALL BE SUBJECT TO THE DISCRETION OF DIFFUSION'S BOARD OF DIRECTORS AND, IF THE MERGER AGREEMENT IS STILL IN EFFECT AT SUCH TIME, WITH SUCH RATIO TO BE MUTUALLY AGREED UPON BY DIFFUSION AND EIP PRIOR TO THE EFFECTIVE TIME, ASSUMING BOTH PARTIES AGREE THAT THE IMPLEMENTATION OF THE REVERSE SPLIT IS APPLICABLE AND NECESSARY

General

At the Diffusion special meeting, Diffusion stockholders will be asked to approve the amendment to the certificate of incorporation, as amended, of Diffusion effecting the Reverse Split of the issued shares of Diffusion Common Stock within the range not less than and not greater than (with such ratio, if the Merger Agreement is still in effect, to be mutually agreed upon by Diffusion and EIP prior to the Effective Time and with all amendments within such range (other than the amendment setting forth the ratio selected) being abandoned by Diffusion's board of directors). Upon the effectiveness of the amendment to the certificate of incorporation, as amended, of Diffusion effecting the Reverse Split, or the split effective time, the issued shares of Diffusion Common Stock outstanding immediately prior to the split effective time will be reclassified into a smaller number of shares such that a Diffusion stockholder will own one new share of Diffusion Common Stock for each to shares of issued Diffusion Common Stock held by that stockholder immediately prior to the split effective time. The ultimate ratio will be based on a number of factors, including market conditions, existing and expected trading prices for Diffusion Common Stock and the listing requirements of the Nasdaq Capital Market.

The form of the amendment to the certificate of incorporation, as amended, of Diffusion to effect the Reverse Split, as more fully described below, will effect the Reverse Split but will not change the number of authorized shares of Diffusion Common Stock or Diffusion preferred stock, or the par value of Diffusion Common Stock or Diffusion preferred stock.

Purpose

Diffusion's board of directors approved the proposal approving the amendment to the certificate of incorporation, as amended, of Diffusion effecting the Reverse Split for the following reasons:

- Diffusion's board of directors believes effecting the Reverse Split may be an effective means of maintaining the listing of the combined company's post-merger common stock on the Nasdaq Capital Market and avoiding a delisting of Diffusion Common Stock from the Nasdaq Capital Market in the future, including, if Diffusion's stock price is less than \$4.00 per share at the time of Closing, to comply with the initial listing requirements of the Nasdaq Capital Market in accordance with Nasdaq Rule 5110(a);
- Diffusion's board of directors believes a higher stock price may help generate investor interest in Diffusion and help Diffusion attract and retain employees;
- if the Reverse Split successfully increases the per share price of Diffusion Common Stock, Diffusion's board of directors believes this increase may increase trading volume in Diffusion Common Stock and facilitate future financings by Diffusion.

One of the effects of the Reverse Split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in Diffusion's management being able to issue more shares without further stockholder approval, as further illustrated in the table below. The Reverse Split will not affect the number of authorized shares of Diffusion Common Stock or Diffusion preferred stock, which will continue to be authorized pursuant to the certificate of incorporation, as amended, of Diffusion, thus the Reverse Split will have the effect of increasing the number of authorized but unissued shares of Diffusion Common Stock. There are no shares of Diffusion preferred stock currently outstanding. Diffusion currently has no plans, commitments, arrangements, understandings or agreements to issue shares, other than pursuant to the Merger Agreement, and to satisfy obligations under the Diffusion stock options and restricted stock units from time to time as these stock options and restricted stock units, respectively, are exercised. The additional authorized shares of common stock will provide the combined company with the flexibility to consider and respond to future business opportunities and needs as they arise, including but not limited to, equity offerings; financings; potential strategic transactions, including mergers, acquisitions and business combinations; stock dividends; stock splits; grants under equity compensation plans; and other general corporate transactions.

Requirements for Nasdaq Listing

Diffusion Common Stock is listed on the Nasdaq Capital Market under the symbol “*DDFN*.” As further described elsewhere in this proxy statement/prospectus/information statement under the heading, “*The Merger Agreement – Conditions to the Closing of the Merger*,” under the terms of the Merger Agreement, one of the conditions to the closing of the Merger is that the existing shares of Diffusion Common Stock shall have been continually listed on Nasdaq as of and from the date of the Merger Agreement through the closing date of the Merger and the shares of Diffusion Common Stock to be issued in the Merger pursuant to the Merger Agreement shall have been approved for listing, subject to official notice of issuance, on Nasdaq after the closing. In April 2023, Diffusion received written notice from the Staff of the Nasdaq listing qualifications department that the Staff has determined that, in connection with the proposed Merger and pursuant to Nasdaq Listing Rule 5110(a), the combined company will be required to satisfy all of Nasdaq’s initial listing criteria prior to consummation of the Merger in order to obtain such approval. Diffusion currently meets, and anticipates that it will meet at the Effective Time, each of the initial listing requirements for the Nasdaq Capital Market under the “Equity Standard” set forth in Nasdaq Rule 5505(b)(1) other than requirements that the company’s listed securities have (i) a bid price of at least \$4.00 and (ii) an aggregate market value of unrestricted publicly held shares of at least \$15.0 million.

On May 5, 2023, the closing price of the Diffusion Common Stock as reported by Nasdaq was \$3.81, resulting in an aggregate market value of unrestricted publicly held shares of less than \$10.0 million. Diffusion is required pursuant to the terms of the Merger Agreement to submit to its stockholders a proposal to approve an amendment to its certificate of incorporation to authorize the Diffusion board of directors to effect the Reverse Split of all outstanding shares of Diffusion Common Stock. The Reverse Split, if approved by Diffusion stockholders, may be implemented by the Diffusion board of directors in an effort to increase the per-share market price of Diffusion Common Stock above the minimum bid price requirement under Nasdaq rules so that the listing of the combined company and the shares of Diffusion Common Stock being issued in the Merger on Nasdaq will be approved. As required by Nasdaq Marketplace Rule 5110 to be filed in connection with the Merger, Diffusion has filed an initial listing application with Nasdaq to seek listing on the Nasdaq Capital Market or other appropriate Nasdaq trading market at the Effective Time.

If the Reverse Split Proposal is not approved and Diffusion is not otherwise able to satisfy these initial listing requirements at the time of closing of the Merger, Nasdaq may not approve the listing of the combined company and the shares of Diffusion Common Stock that would be issued in the Merger, which would entitle EIP to terminate the Merger Agreement due to Diffusion’s failure to satisfy the associated closing condition. Even if Diffusion and EIP agreed to waive the requirement that the Nasdaq application be accepted for listing prior to the consummation of the Merger, and their respective boards of directors determined to proceed with the closing of the Merger in its absence, Nasdaq may notify the combined company of its determination to delist the company’s securities based upon the failure to satisfy the initial inclusion criteria. The combined company may appeal the determination to a hearings panel, which will stay the delisting action pending a panel decision. If the combined company does not appeal the determination, its common stock will be delisted. Any potential suspension of the shares of common stock from Nasdaq would likely result in decreased liquidity and increased volatility for the combined company’s common stock and would adversely affect the combined company’s ability to raise additional capital or to enter into strategic transactions. Any potential suspension of the shares of common stock from Nasdaq would also make it more difficult for stockholders to sell the combined company’s common stock in the public market.

Potential Increased Investor Interest

On May 5, 2023, Diffusion Common Stock closed at \$3.81 per share. Many institutional investment funds, family offices, and other private wealth managers have investment policies prohibiting them from buying and/or holding lower-priced stocks in their portfolios, which may prohibit them from investing in Diffusion Common Stock at the current price. In addition, brokerage firms may be reluctant to recommend lower-priced securities to their clients due to the perceived risk profile and/or because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Although there would be a lower number of shares of common stock outstanding following the Reverse Split, a larger number of investors participating in the market for the stock may provide support to the degree of liquidity in the market for Diffusion Common Stock.

There are risks associated with the Reverse Split, including that the Reverse Split may not result in an increase in the per share price of Diffusion Common Stock. Diffusion cannot predict whether the Reverse Split will increase the market price for Diffusion Common Stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Diffusion Common Stock after the Reverse Split will rise in proportion to the reduction in the number of shares of Diffusion Common Stock outstanding before the Reverse Split;
- the Reverse Split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;
- the Reverse Split will result in a per share price that will increase the ability of Diffusion to attract and retain employees; or
- the market price per share will either exceed or remain in excess of the \$1.00 minimum bid price as required by Nasdaq for continued listing, that Diffusion will otherwise meet the requirements of Nasdaq for inclusion for trading on the Nasdaq Capital Market, including the \$4.00 minimum bid price at the Effective Time.

The market price of Diffusion Common Stock will also be based on performance of Diffusion and other factors, some of which are unrelated to the number of shares outstanding. If the Reverse Split is effected and the market price of Diffusion Common Stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of Diffusion may be greater than would occur in the absence of the Reverse Split. Furthermore, the liquidity of Diffusion Common Stock could be adversely affected by the reduced number of shares that would be outstanding after the Reverse Split.

Criteria to be Used for Determining Whether to Implement the Reverse Split

In determining whether to implement the Reverse Split and which reverse stock split ratio to implement, if any, following receipt of stockholder approval of the Reverse Split Proposal, Diffusion, also if the Merger Agreement is still in effect, EIP, may consider, among other things, various factors, such as:

- the historical trading price and trading volume of Diffusion Common Stock;
- the then-prevailing trading price and trading volume of Diffusion Common Stock and the expected impact of the Reverse Split on the trading market for Diffusion Common Stock in the short- and long-term;
- the ability of Diffusion to continue its listing on the Nasdaq Capital Market and/or meet the initial listing requirements of Nasdaq in connection with the Merger;
- the number of shares of Diffusion Common Stock outstanding;
- the anticipated impact of the Reverse Split on our ability to raise additional financing;
- which Reverse Split ratio would result in the least administrative cost to Diffusion; and
- prevailing general market and economic conditions.

Principal Effects of the Reverse Split

The amendment to the certificate of incorporation, as amended, of Diffusion effecting the Reverse Split is attached as *Annex B* to this proxy statement/prospectus/information statement.

The Reverse Split will be effected simultaneously for all outstanding shares of Diffusion Common Stock. The Reverse Split will affect all of the Diffusion stockholders uniformly and will not affect any stockholder's percentage ownership interests in Diffusion, except to the extent that the Reverse Split results in any of the Diffusion stockholders owning a fractional share. The Reverse Split will not change the terms of Diffusion Common Stock. After the Reverse Split, the shares of Diffusion Common Stock will have the same voting rights and rights to dividends and distributions and will be identical in all other respects to the Diffusion Common Stock now authorized, which is not entitled to preemptive or subscription rights, and is not subject to conversion, redemption or sinking fund provisions. Diffusion Common Stock issued pursuant to the Reverse Split will remain fully paid and nonassessable. The Reverse Split does not affect the total proportionate ownership of the combined company following the Merger. The Reverse Split will not affect Diffusion continuing to be subject to the periodic reporting requirements of the Exchange Act.

As an example, the following table illustrates certain effects of a 1-for- and a 1-for- reverse stock split (without giving effect to the treatment of fractional shares) on the combined company's capitalization:

	Prior to Reverse Stock Split	After 1- for- Reverse Stock Split	After 1- for- Reverse Stock Split
Authorized common stock	1,000,000,000		
Common stock issued and outstanding immediately prior to Merger	2,039,878(1)		
Common stock issuable upon exercise of outstanding warrants	88,252(2)		
Common stock issuable upon exercise of outstanding stock options and settlement of restricted stock units	106,957(2)		
Common stock reserved for issuance for future grants under 2015 Equity Plan	141,096(2)		
Common stock authorized but unissued and unreserved/unallocated	997,623,817		
Estimated shares to be issued to former EIP stockholders at closing of the Merger, if consummated	6,932,575(3)		
Estimated common stock issued and outstanding immediately following closing of the Merger, if consummated	8,972,453(3)		

(1) Based on shares of Diffusion Common Stock issued and outstanding as of the date of the Merger Agreement.

(2) As of March 31, 2023

(3) Based on an estimated Exchange Ratio of 0.1860. For a further discussion of the calculation of the Exchange Ratio and the assumptions underlying this estimate, see "The Merger Agreement — Merger Consideration and Exchange Ratio" beginning on page 146 of this proxy statement/prospectus/information statement.

In addition, if the Reverse Split is implemented, it will increase the number of Diffusion stockholders who own "odd lots" of fewer than 100 shares of Diffusion Common Stock. Brokerage commission and other costs of transactions in odd lots are generally higher than the costs of transactions of more than 100 shares of common stock. Accordingly, the Reverse Split may not achieve the desired results of increasing marketability and liquidity of Diffusion Common Stock that have been described above.

After the effective date of the Reverse Split, Diffusion Common Stock would have a new committee on uniform securities identification procedures, or CUSIP number, a number used to identify Diffusion Common Stock.

Diffusion Common Stock is currently registered under Section 12(b) of the Exchange Act, and Diffusion is subject to the periodic reporting and other requirements of the Exchange Act. The Reverse Split will not affect the registration of Diffusion Common Stock under the Exchange Act.

The Reverse Split will have no effect on Diffusion's authorized preferred stock, which will remain at 30 million shares, none of which are issued or outstanding.

Certain Risks Associated with the Reverse Split

For a discussion of risks associated with the Reverse Split, see “*Risk Factors – Risks Related to the Reverse Split*” elsewhere in this proxy statement/prospectus/information statement.

Procedure for Effecting Reverse Split and Exchange of Stock Certificates

If the Reverse Split is approved by Diffusion stockholders, and if at such time Diffusion’s board of directors still believes that the Reverse Split is in the best interests of Diffusion and its stockholders, Diffusion’s board of directors will determine the ratio of the Reverse Split to be implemented. The Reverse Split will become effective as of 12:01 a.m., Eastern Time on the date specified in the Certificate of Amendment as filed with the office of the Secretary of State of the State of Delaware (the “Reverse Split Effective Time”). Diffusion’s board of directors will determine the exact timing of the filing of the Certificate of Amendment based on its evaluation as to when the filing would be the most advantageous to Diffusion and its stockholders. If Diffusion’s board of directors does not decide to implement the Reverse Split prior to December 31, 2023, the authority granted in this proposal to implement the Reverse Split will terminate. Except as described below under the section titled “—*Fractional Shares*” below, at the Reverse Split Effective Time, each number of issued and outstanding pre-Reverse Split shares that Diffusion’s board of directors has determined will be combined into one post-Reverse Split share and will, automatically and without any further action on the part of our stockholders, be combined into and become one share of common stock, and each certificate which, immediately prior to the Reverse Split Effective Time represented pre-Reverse Split shares, will be deemed for all corporate purposes to evidence ownership of post-Reverse Split shares.

Book-Entry Shares

If the Reverse Split is effected, Diffusion stockholders who hold uncertificated shares (i.e., shares held in book-entry form and not represented by a physical stock certificate), either as direct or beneficial owners, will have their holdings electronically adjusted automatically by our transfer agent (and, for beneficial owners, by their brokers or banks that hold in “street name” for their benefit, as the case may be) to give effect to the Reverse Split. Diffusion stockholders who hold uncertificated shares as direct owners will be sent a statement of holding from our transfer agent that indicates the number of post-Reverse Split shares of Diffusion Common Stock owned in book-entry form. If the proposed Reverse Split is approved and effected, we intend to treat Diffusion Common Stock held by Diffusion stockholders in “street name,” through a bank, broker or other nominee, in the same manner as Diffusion stockholders whose shares are registered in their own names. Banks, brokers or other nominees will be instructed to effect the Reverse Split for their customers holding Diffusion Common Stock in “street name.” However, these banks, brokers or other nominees may have different procedures than registered stockholders for processing the Reverse Split. If a Diffusion stockholder holds shares of Diffusion Common Stock with a bank, broker or other nominee and have any questions in this regard, you are encouraged to contact your bank, broker or other nominee.

Certificated Shares

As soon as practicable after the Reverse Split Effective Time, Diffusion stockholders will be notified that the Reverse Split has been effected. We expect that Diffusion’s transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-Reverse Split shares will be asked to surrender to the exchange agent certificates representing pre-Reverse Split shares in exchange for certificates representing post-Reverse Split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Diffusion or its exchange agent. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder’s outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-Reverse Split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-Reverse Split shares.

Fractional Shares

No fractional shares will be issued in connection with the Reverse Split. Diffusion stockholders of record who otherwise would be entitled to receive fractional shares will have that rounded up to one additional whole share.

Diffusion stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders may reside, where Diffusion is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the Reverse Split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by us or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, Diffusion stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

Accounting Consequences; Effect on Par Value

The Reverse Split will affect the Diffusion Common Stock capital account on Diffusion’s balance sheet and will not affect the par value of the Diffusion Common Stock, which will remain at \$0.001 per share. Because the par value of Diffusion Common Stock will remain unchanged at the Reverse Split Effective Time, if approved and implemented, the components that make up the Diffusion Common Stock capital account will change by offsetting amounts. Depending on the ratio of the Reverse Split that is determined to be implemented, the stated capital component will be reduced proportionately based upon the Reverse Split and the additional paid-in capital component will be increased with the amount by which the stated capital is reduced subject to minor adjustments for fractional shares. Immediately after the Reverse Split, the per share net income or loss and net book value of the Diffusion Common Stock will be increased because there will be fewer shares of Diffusion Common Stock outstanding. All historic share and per share amounts in Diffusion’s financial statements and related footnotes will be adjusted accordingly for the Reverse Split.

Potential Anti-Takeover Effect; No Going Private Transaction

Even though the proposed Reverse Split would result in an increased proportion of unissued authorized shares to issued shares, which could, under certain circumstances, have an anti-takeover effect (for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the board of directors or contemplating a tender offer or other transaction for the combination of Diffusion with another company), the Reverse Split is not being proposed in response to any effort of which Diffusion is aware to accumulate shares of Diffusion Common Stock or obtain control of the company, nor is it part of a plan by management to recommend a series of similar amendments to the Diffusion’s board of directors and its stockholders other than, to the extent applicable and otherwise described in this proxy statement/prospectus/information statement, the transactions contemplated by the Merger Agreement. Other than the proposals being submitted to the Diffusion stockholders for their consideration at the Diffusion special meeting, Diffusion’s board of directors does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Diffusion. Furthermore, notwithstanding the decrease in the number of outstanding shares following the proposed Reverse Split, Diffusion’s board of directors does not intend for this transaction to be the first step in a “going private transaction” within the meaning of Rule 13e-3 of the Exchange Act.

For more information, please see the sections titled “*Risk Factors — Risks Related to Ownership of Diffusion Common Stock if the Merger is Not Completed*” beginning on page 51 and “*Description of Diffusion Capital Stock — Anti-Takeover Provisions of Diffusion’s Certificate of Incorporation, Bylaws and Delaware Law*” beginning on page 282.

Material U.S. Federal Income Tax Consequences of the Reverse Split

The following is a discussion of certain material U.S. federal income tax consequences of the Reverse Split to U.S. Holders (as defined below) that hold shares of Diffusion Common Stock as capital assets for U.S. federal income tax purposes.

This summary does not address all aspects of U.S. federal income taxation that may be relevant to U.S. Holders in light of their particular circumstances or to U.S. Holders who may be subject to special tax treatment under the Code, including, without limitation dealers or traders in securities, commodities or foreign currency; banks, thrifts, insurance companies, and other financial institutions; traders that mark-to-market their securities; tax-exempt organizations or governmental organizations; regulated investment companies; real estate investment trusts; tax-deferred or other retirement accounts; persons whose functional currency is not the U.S. dollar; persons who hold Diffusion Common Stock as part of a “straddle,” “hedge,” “conversion transaction” or other risk reduction transaction; persons who hold or receive Diffusion Common Stock pursuant to the exercise of compensatory stock options, the vesting of previously restricted shares of stock or otherwise as compensation; any entity or arrangement that is a partnership or other pass-through entity for U.S. federal income tax purposes; “expatriated entities”; or certain former citizens or long-term residents of the United States.

This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the IRS in effect as of the date hereof, all of which are subject to change, possibly with retroactive effect, or differing interpretations. Any such change may cause the U.S. federal income tax consequences of the Reverse Split to vary substantially from the consequences summarized below. Diffusion has not sought any ruling from the IRS with respect to the statements made and the conclusions reached in this discussion, and there can be no assurance that the IRS will agree with these statements and conclusions. The effects of other U.S. federal tax laws, such as estate and gift tax laws, the alternative minimum tax and the 3.8% tax on net investment income, and any applicable state, local, or foreign tax laws or the tax consequences of events occurring prior to, concurrently with or after the Merger (whether or not such transactions are in connection with the Merger) are not discussed.

The state and local tax consequences of a reverse split may vary as to each U.S. Holder, depending on the jurisdiction in which such U.S. Holder resides. This discussion should not be considered as tax or investment advice, and the tax consequences of the Reverse Split may not be the same for all U.S. Holders. U.S. Holders should consult their own tax advisors to understand their individual federal, state, local and foreign tax consequences to them of the reverse stock split.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of shares of Diffusion Common Stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if either a court within the United States is able to exercise primary supervision over the administration of such trust and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of such trust, or the trust has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold Diffusion Common Stock through such entities. If a partnership (or other entity or arrangement treated as a partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of Diffusion Common Stock, the U.S. federal income tax treatment of a partner or member in such partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity and its partners or members. Partnerships or other pass-through entities or arrangements holding Diffusion Common Stock and partners or members in such entities or arrangements are urged to consult their own tax advisors.

Tax Consequences of the Reverse Split

The Reverse Split should constitute a “recapitalization” for U.S. federal income tax purposes under Section 368(a)(1)(E) of the Code. As a result, a U.S. Holder of shares of Diffusion Common Stock should not recognize any gain or loss for U.S. federal income tax purposes as a result of the Reverse Split. A U.S. Holder’s aggregate tax basis in shares of Diffusion Common Stock received in the Reverse Split should equal the U.S. Holder’s aggregate tax basis in the shares of Diffusion Common Stock exchanged in the Reverse Split. In addition, each U.S. Holder’s holding period for the shares of Diffusion Common Stock the U.S. Holder receives in the Reverse Split should include the U.S. Holder’s holding period for the shares of Diffusion Common Stock exchanged in the Reverse Split. U.S. Holders of shares of Diffusion Common Stock acquired on different dates and at different prices should consult their own tax advisors regarding the allocation of the tax basis and holding period of such shares.

Information Reporting and Backup Withholding

A U.S. Holder of shares of Diffusion Common Stock may be subject to information reporting and backup withholding in connection with the Reverse Split, unless the U.S. Holder is an exempt recipient. Backup withholding generally will apply to such payments if the U.S. Holder fails to furnish a correct taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Each U.S. Holder of shares of Diffusion Common Stock should properly complete and sign, and deliver, an IRS Form W-9 in order to provide the information and certification necessary to avoid backup withholding, or otherwise establish an applicable exemption in a manner acceptable to the paying agent. U.S. Holders of shares of Diffusion Common Stock should consult their own tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption. Backup withholding is not an additional tax. Any amounts withheld will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Reservation of Right to Abandon Reverse Split if Approved

Diffusion reserves the right to not file the certificate of amendment and to abandon the Reverse Split without further action by Diffusion stockholders at any time before the effectiveness of the filing with the Secretary of the State of Delaware thereof, even if the authority to effect these amendments is approved by stockholders at the Diffusion special meeting. By voting in favor of the Reverse Split, a Diffusion stockholder is expressly also authorizing Diffusion's board of directors to delay, not proceed with, and abandon, these proposed amendments if it should so decide, in its sole discretion, that such action is in the best interests of Diffusion stockholders.

Certificate of Amendment to Diffusion's Certificate of Incorporation, As Amended

If the Reverse Split is approved and implemented, the following paragraph shall be added at the end of subsection A of Article IV of Diffusion's certificate of incorporation, as amended:

“Effective upon the effective time of this Certificate of Amendment of the Certificate of Incorporation with the Secretary of State of the State of Delaware (the ‘Effective Time’), each [intentionally left blank] shares¹ of Common Stock issued and outstanding immediately prior to the Effective Time shall, automatically and without the necessity of any further action, be changed, reclassified and combined into one (1) share of Common Stock (the ‘Reverse Stock Split’). No fractional shares shall be issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional shares of Common Stock shall have that rounded up to one additional whole share. Each certificate that immediately prior to the Effective Time represented shares of Common Stock (‘Old Certificates’), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional shares as described above.

1 This amendment approves the reverse stock split of the Corporation's common stock, at a ratio in the range of - to -for-one. By approving this amendment, the stockholders of the Corporation would be deemed to approve any ratio within the range referred to above.”

The certificate of amendment attached hereto as *Annex B* reflects the changes that will be made to Diffusion's certificate of incorporation if the Reverse Split is approved and Diffusion's board of directors decides to implement it.

Required Vote; Recommendation of Board of Directors

The affirmative vote of the holders of a majority of the shares of Diffusion Common Stock outstanding on the record date for the Diffusion special meeting is required to approve the amendment to the certificate of incorporation of Diffusion effecting the Reverse Split.

THE DIFFUSION BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT DIFFUSION STOCKHOLDERS VOTE “FOR” THE REVERSE SPLIT PROPOSAL TO APPROVE AN AMENDMENT TO THE CERTIFICATE OF INCORPORATION, AS AMENDED, OF DIFFUSION TO EFFECT THE REVERSE SPLIT WITHIN A RANGE OF ONE NEW SHARE FOR NOT LESS THAN AND NOT GREATER THAN SHARES OUTSTANDING AT ANY TIME PRIOR TO DECEMBER 31, 2023, THE IMPLEMENTATION AND TIMING OF WHICH SHALL BE SUBJECT TO THE DISCRETION OF DIFFUSION'S BOARD OF DIRECTORS AND, IF THE MERGER AGREEMENT IS STILL IN EFFECT AT SUCH TIME, WITH SUCH RATIO TO BE MUTUALLY AGREED UPON BY DIFFUSION AND EIP PRIOR TO THE EFFECTIVE TIME, ASSUMING BOTH PARTIES AGREE THAT THE IMPLEMENTATION OF THE REVERSE SPLIT IS APPLICABLE AND NECESSARY.

DIFFUSION PROPOSAL NO. 3 (THE POSTPONEMENT PROPOSAL):

APPROVE A POSTPONEMENT OR ADJOURNMENT OF THE SPECIAL MEETING, IF NECESSARY, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF THE PROPOSALS SET FORTH ABOVE

If Diffusion fails to receive a sufficient number of votes to approve the Stock Issuance Proposal and/or the Reverse Split Proposal, Diffusion may propose to adjourn the Diffusion special meeting for the purpose of soliciting additional proxies to approve the Stock Issuance Proposal and/or the Reverse Split Proposal. Diffusion currently does not intend to propose adjournment at the Diffusion special meeting if there are sufficient votes to approve the Stock Issuance Proposal and the Reverse Split Proposal.

If on the date of the Diffusion special meeting, or a date preceding the date on which the Diffusion special meeting is scheduled, Diffusion reasonably believes that (i) it will not receive proxies sufficient to obtain the required vote to approve the proposals, whether or not a quorum would be present or (ii) it will not have sufficient shares of Diffusion Common Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Diffusion special meeting, Diffusion may postpone or adjourn, or make one or more successive postponements or adjournments of, the Diffusion special meeting as long as the date of the Diffusion special meeting is not postponed or adjourned more than an aggregate of 60 calendar days in connection with any postponements or adjournments.

Required Vote; Recommendation of Board of Directors

Presuming a quorum is present, the affirmative vote of the holders of a majority of the shares of Diffusion Common Stock present in person or represented by proxy at the Diffusion special meeting and entitled to vote generally on the subject matter is required for approval of this proposal.

DIFFUSION'S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE DIFFUSION STOCKHOLDERS VOTE "FOR" THE APPROVAL OF THE POSTPONEMENT PROPOSAL.

DIFFUSION BUSINESS

Unless the context otherwise requires, all references in this section to “we,” “our,” “us,” or “Diffusion” refer to the business of Diffusion Pharmaceuticals Inc. prior to the consummation of the Merger.

Overview

Diffusion is a biopharmaceutical company that has historically focused on developing novel therapies that may enhance the body’s ability to deliver oxygen to the areas where it is needed most. Diffusion’s most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine’s most intractable and difficult-to-treat conditions, including hypoxic solid tumors like GBM.

Current Strategy

Strategic Review Process and Proposed Merger with EIP

In early 2022, Diffusion identified the pursuit of an opportunistic transaction with the potential to complement and diversify its portfolio of product candidates as one of its key strategic objectives intended to enhance long-term value for its stockholders. In pursuit of this objective, in July 2022, Diffusion engaged CG as its financial advisor to support Diffusion’s process and, in October 2022, following further deterioration of the public capital markets throughout 2022 and the corresponding increase in the cost of capital for small biopharmaceutical companies, Diffusion publicly announced its board of directors’ authorization of an expanded evaluation and review of potential strategic transactions, including a joint venture, licensing, merger, reverse merger, sale or divestiture of some of proprietary technologies or a sale of Diffusion, among others. These efforts are further described in the section titled “*The Merger – Background of the Merger,*” beginning on page 106 of this proxy statement/prospectus/information statement.

On March 30, 2023, Diffusion, Merger Sub and EIP entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into EIP, with EIP surviving the merger as the wholly-owned subsidiary of the combined company. The Merger Agreement and the transactions contemplated thereby are described in detail elsewhere in this proxy statement/prospectus/information statement.

If the Merger is completed, the combined company will focus on developing EIP’s product candidates, which are described on page 196 under the section titled “*EIP Business.*” If the Merger is not completed, Diffusion will reconsider its strategic alternatives and may pursue one of the following courses of action, which Diffusion currently believes are the most likely alternatives if the Merger is not completed:

- Pursue another strategic transaction similar to the Merger. Diffusion may resume its process of evaluating other companies interested in pursuing a strategic transaction with Diffusion and, if a candidate is identified, focus its attention on negotiating and completing such a transaction with such candidate.
- Dissolve and liquidate its assets. If Diffusion is unable, or does not believe that it is able, to find a suitable candidate for another strategic transaction, Diffusion may dissolve and liquidate its assets. In the event of dissolution, Diffusion would be required to pay all of its debts and contractual obligations and to set aside certain reserves for potential future claims. If Diffusion dissolves and liquidates its assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to Diffusion’s stockholders after paying Diffusion’s debts and other obligations and setting aside funds for its reserves.

Diffusion’s Historical Development Program: Trans Sodium Crocetin

Prior to the initiation of Diffusion’s strategic review process and entering into the Merger Agreement with EIP, Diffusion’s core focus was the development and commercialization of novel therapies that enhance the body’s ability to deliver oxygen to areas where it is needed most and improve treatment outcomes for patients suffering from conditions complicated by hypoxia. Diffusion’s development efforts have been primarily focused on advancing its most advanced product candidate, TSC, and we continue to believe TSC has potential benefits for patients, particularly as an adjuvant treatment to standard of care therapy for GBM and other hypoxic solid tumors. In connection with Diffusion’s strategic review process and pending its conclusion, we have paused significant portions of Diffusion’s TSC development activities, including initiation of Diffusion’s previously announced Phase 2 study of TSC in newly diagnosed GBM patients.

Trans Sodium Crocetinate: Enhancing Oxygen, Fueling Life

Diffusion believes TSC is the first therapeutic candidate specifically designed to enhance the efficiency of the oxygen diffusion process. By supporting normal, physiologic levels of oxygen diffusion at the uptake and delivery points of the circulatory system, Diffusion believes TSC may have the ability to improve the current standard-of-care treatment for conditions complicated by hypoxia. Furthermore, in animal models, TSC's diffusion-enhancing mechanism of action has been observed to affect hypoxic tissue preferentially while avoiding excessive oxygen-related tissue toxicity.

TSC's Demonstrated Clinical Safety Profile

TSC has been observed to be safe and well-tolerated at a variety of doses in over 220 subjects included in clinical studies conducted to date, including those studies that evaluated the effects of TSC in patients with medical conditions often complicated by hypoxia, such as GBM, peripheral artery disease with intermittent claudication, stroke, COVID-19, and interstitial lung disease. Diffusion has also obtained valuable new data from its COVID Trial and Oxygenation Trials demonstrating TSC's safety and effects on oxygenation at higher doses and increased dosing frequencies compared to those previously evaluated.

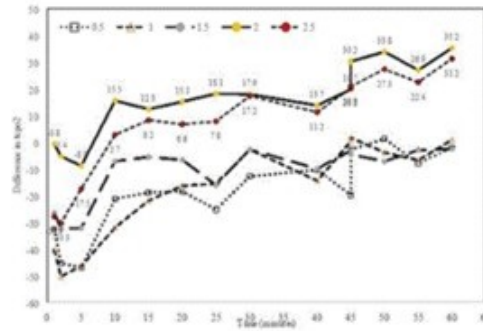
The TSC Oxygenation Trials: Evaluating the Clinical Effects of TSC

Diffusion's Oxygenation Trials, conducted during 2021 and 2022, were a series of three, short-term clinical studies using experimental models to evaluate the clinical effects of TSC on oxygenation. Each of these three studies was designed to look at the effects of TSC on a different component of the oxygenation pathway and fill information gaps related to the effects of TSC on tissue oxygen levels and other direct clinical parameters related to oxygen levels. Diffusion believes the results of the Oxygenation Trials provide proof of concept of TSC's effects on tissue oxygenation, in addition to supplementing Diffusion's knowledge with new information related to TSC's pharmacokinetics and pharmacodynamics.

TCOM Trial: TSC's Effects on Peripheral Tissue Oxygenation

In June 2021, Diffusion reported a positive trend among patients who received TSC, when compared to placebo, in peripheral tissue oxygenation measured with the use of a transcutaneous oxygen monitoring (TCOM) device. These results can be seen in the figure below which was created during a supplemental analysis of the TCOM Trial results by subtracting the median response observed in the TCOM Trial's placebo group from the median response observed in each TSC dosage group at each of the measurement times during the one-hour period following dosing.

These data highlight the persistent increase in peripheral tissue oxygenation relative to that observed in the placebo group through the duration of the one-hour measurement period following TSC administration, particularly at the two highest TSC doses tested (2.0 mg/kg and 2.5 mg/kg administered intravenously).



Effects of TSC on transcutaneous oxygen pressure.

Altitude Trial: TSC's Effects Under Induced Hypoxic Conditions

In June 2022, Diffusion reported that, following exercise under hypoxic (i.e., simulated high altitude) conditions, participants in Diffusion's Altitude Trial treated with the highest dose of TSC (2.5 mg/kg) demonstrated an effect on physiologic indicators of enhanced oxygenation when compared to placebo, including an increase in plasma pH and a decrease in plasma lactate, both at the end of the exercise period and at 10 minutes post-exercise. Diffusion believes these data suggest the 2.5 mg/kg dose of TSC decreased blood acidity (i.e., lactic acid accumulation) and enhanced metabolic recovery at 10 minutes after completion of exercise under the stressful conditions of exercise at simulated high altitude.

Additional positive results observed in the Altitude Trial included:

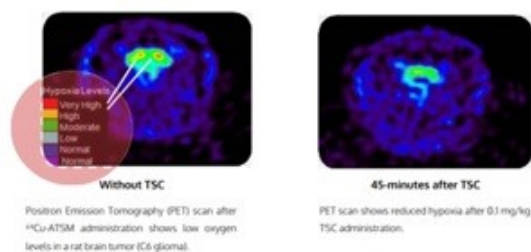
- Positive effects on lactate and pH relative to participants' baseline measurements were observed among the TSC 2.5 mg/kg dose cohort at the end of the exercise period;
- A "carry-over" effect was observed in participants who received TSC in the first treatment ("ascent") of the day versus those who received placebo first and TSC for the second ascent; and
- The 2.5 mg/kg dose appeared to have a positive effect on post-exercise recovery based on comparison of the measurements for pH, lactate, oxygen saturation (SpO₂) and other markers of oxygenation at 10 minutes post-exercise versus last exercise measurements.

ILD-DLCO Trial: TSC's Effects on Oxygen Transfer Efficiency

In December 2021, Diffusion announced dosing of the first patients in Diffusion's ILD-DLCO Trial, which was designed to evaluate the effects of TSC in certain patients with previously diagnosed ILD using the diffusion of carbon monoxide through the lungs, or DLCO, as a surrogate measure of oxygen transfer efficiency. In August 2022, in order to dedicate more of Diffusion's human and other resources to Diffusion's strategic review process and ongoing challenges enrolling patients in clinical trials for respiratory indications due to the COVID-19 pandemic, Diffusion made the decision to terminate recruitment and enrollment in the ILD-DLCO Trial and wind the trial down.

TSC's Potential as Supplement to Standard of Care Therapy for Hypoxic Solid Tumors

Reduced hypoxia in rat C6 glioma brain tumors without hyper-oxygenation of normal tissue¹



¹Sheehan, et al. *J Neurosurg*. 2011; 115(4). <https://doi.org/10.3171/2011.5.JNS101954>

Positron emission tomography scans showing reduction in hypoxia in a rat C6 glioma brain tumor model 45 min after TSC administration.

As seen in the positron emission tomography scans above, Diffusion has previously obtained and published evidence supporting TSC's ability to enhance oxygenation of C6 glioma tumors in animals. Diffusion also has obtained clinical evidence of TSC's effects in unresectable GBM tumors from Diffusion's previously completed Phase 2 clinical trial evaluating 59 patients with newly diagnosed GBM. Although not prospectively defined, a post hoc subgroup analysis of inoperable patients suggested a higher proportion of TSC-treated patients survived at two years compared to those in the historical control group. Based upon these data, Diffusion made the decision to pursue the development of TSC as a treatment for hypoxic solid tumors when administered with standard-of-care radiation therapy and chemotherapy.

Diffusion's Phase 2 GBM Trial

GBM is an aggressive, deadly, and treatment-resistant type of malignant brain tumor, affecting approximately 13,000 newly diagnosed patients each year in the United States. Few treatment options are available for patients with GBM, and none have extended life expectancy beyond a few months. In fact, according to the National Brain Tumor Society, the five-year survival rate for GBM is only 6.8 percent with an average survival time of eight months. Despite recent advances in treatment modalities, Diffusion believes an effective treatment for GBM remains a significant unmet medical need.

Based upon data from the inoperable patient subgroup in Diffusion's Phase 2 GBM trial and guidance from the FDA received at Diffusion's End-of-Phase-2 meeting, Diffusion initiated a Phase 2b/3 GBM Trial in patients with newly diagnosed inoperable GBM in December 2017. The trial was designed to enroll 236 patients, split evenly between the TSC treatment arm and the control arm, with TSC to be administered in combination with standard of care radiotherapy and temozolomide, an anti-cancer chemotherapy drug, during the adjuvant treatment chemotherapy period. The trial began with a 19 patient, FDA-mandated, open-label, dose-escalation safety run-in phase for which enrollment was completed in 2019. At a meeting in the third quarter of 2019, the data safety monitoring board for the trial concluded that no adverse safety signal was present and unanimously recommended the GBM Trial continue as planned. However, due to a lack of financial resources at the time, Diffusion did not initiate the randomized portion of the study.

Diffusion's Hypoxic Solid Tumor Program

In July 2022, Diffusion announced alignment with the FDA on the design of an open-label, dose-escalation, Phase 2 safety and efficacy study of TSC administered with standard of care to newly diagnosed GBM patients, designated "Study 200-208." The design of this trial has been reviewed and cleared to proceed by the FDA's Office of Oncologic Diseases. Key elements of the Study 200-208 trial design include the following:

- Innovative incorporation of PET scans and hypoxia-specific radiotracers to evaluate the oxygenating enhancing effects of TSC on tumor hypoxia;
- PET scan data readouts from the first phase of the trial are expected to be available within one year of the first patient being dosed, multiple years earlier than the survival data readout in most clinical trials involving hypoxic solid tumor patients; and
- Building upon the knowledge obtained in Diffusion's COVID and Oxygenation Trials, patients in Study 200-208 would receive TSC at a significantly increased dose (up to 2.5 mg/kg v. 0.25 mg/kg) and frequency (five days/week v. 3 days/week) as compared to Diffusion's prior GBM trials, representing an increase in weekly TSC exposure of nearly 1,700% at the highest potential dose.

As of the date of this proxy statement/prospectus/information statement, the design of Study 200-208 is complete, but in connection with Diffusion's strategic review process and entry into the Merger Agreement with EIP, it has paused significant portions of the TSC development activities including any plans of initiating Study 200-208.

Studies of TSC in Other Conditions Complicated by Hypoxia and Beyond

Beyond cancer, hypoxia is a complicating factor in many other intractable and difficult-to-treat conditions, including cardiovascular diseases, cerebrovascular diseases, respiratory diseases, skin and soft tissue diseases, and neurodegenerative diseases. In addition to Diffusion's oncology programs, Diffusion has previously conducted a variety of preclinical and clinical studies evaluating the effects of TSC in several of these other potential indication areas and conditions complicated by hypoxia, including COVID-19, stroke, peripheral artery disease with intermittent claudication, and Diffusion believes TSC's oxygen-enhancing mechanism of action could potentially provide benefits to patients and individuals suffering from one or more of these or other related indications or conditions.

TSC has also been evaluated in a variety of preclinical models intended to mimic relevant human conditions known to be complicated by hypoxia. In these studies, a variety of positive effects have been observed in connection with TSC administration, including:

- Reducing hypoxia in rat brain tumors without hyper-oxygenation of normal tissue;
- Improving survival in highly lethal adult and pediatric brain tumor models when added to standard of care therapy, including radiotherapy administered either alone or in combination with chemotherapy;
- Improving tissue oxygenation without hyper-oxygenation of normal tissue and reducing infarct size in a rat ischemic stroke model;
- Demonstrating a functional benefit in a rabbit ischemic stroke model, with or without tissue plasminogen activator at one-hour post-clot infection and with tissue plasminogen activator at three hours post-clot infection; and
- Improving levels of arterial partial pressure of blood oxygen in a rat model of acute respiratory distress syndrome.

Product Development

Research and Development

In recent years and prior to commencing its strategic review process, the majority of Diffusion's research and development expenditures have been directed to the development of TSC. For example, during the year ended December 31, 2022, Diffusion incurred approximately \$7.2 million in costs related to research and development of Diffusion's products, a decrease of approximately \$1.3 million compared to the year ended December 31, 2021. The majority of these costs were related to the development of TSC and related personnel, including costs associated with the Oxygenation Trials.

Intellectual Property

Diffusion believes that a strong intellectual property portfolio is critical to a biotechnology company's success. Diffusion is committed to obtaining and maintaining appropriate patent and other protections for Diffusion's products candidates and other technologies, preserving and protecting Diffusion's trade secrets and other confidential and proprietary information, and fiercely defending Diffusion's intellectual property portfolio against any potential infringement by third parties. Diffusion attempts to protect Diffusion's intellectual property through among other things, the filing of applications for patent, trademark, and other appropriate intellectual property protections, the use of confidentiality agreements with consultants, contractors and other third parties, Diffusion's employee policies regarding confidentiality, invention disclosure, and the assignment of inventions, as well as regular meetings of members of Diffusion's internal development and legal teams, which contains key members of Diffusion's management team. Diffusion is also committed to operating its business without infringing on the intellectual property of others.

In general, patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained, with term adjustments or extensions possible in certain cases based on patent office delays or pursuant to certain administrative and legislative exceptions. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

Diffusion has invested significant time, effort, and resources into the development and maintenance of Diffusion's patent portfolio. As of December 31, 2022, Diffusion owned 19 issued U.S. patents and 34 issued non-U.S. patents, and had numerous patent applications pending worldwide including issued patents and applications in major markets such as the U.S., E.U., China, Japan, and India. The normal life (i.e. with no adjustments or extensions) of Diffusion's key issued patents related to the current liquid formulation of TSC extends to 2026, with potential patent term extensions to 2031, and the normal life of Diffusion's patents related to an oral formulation of TSC extends to 2031, with potential patent term extensions to 2036. The normal life of Diffusion's key issued patents related to methods of use of TSC extends to 2037, with potential patent term extensions to 2042. For additional information regarding patent term extensions, see "*Business — Government Regulation— The Hatch-Waxman Amendments — Patent Term Restoration and Marketing Exclusivity*" below. In addition, TSC has been granted Orphan Drug designation by the FDA for the treatment of both GBM and metastatic brain cancer, which may provide Diffusion with a right of exclusivity under certain FDA regulations. For additional information regarding orphan and ultra-orphan designations, see "*Business — Government Regulation — Certain Other FDA Regulations — The Orphan Drug Act of 1983.*"

Chemistry, Manufacturing, and Controls

Diffusion does not currently own or operate any manufacturing facilities. Diffusion has used third-party CMOs to manufacture API, other starting materials, and finished drug product for Diffusion's preclinical studies, although Diffusion does not have any formal agreements at this time with any CMO to cover commercial production of any of Diffusion's product candidates.

Commercial Outlook

Competition

Diffusion's future commercial and competitive outlook is highly dependent on whether or not the Merger with EIP is completed and therefore currently subject to a high degree of uncertainty.

With respect to Diffusion's most advanced legacy product candidate, TSC, current medical options to improve oxygenation without risk of hyper-oxygenation are limited. However, there are several companies currently developing or marketing oxygen enhancing products, therapeutics, or devices that may nevertheless be competitive with TSC, if approved, including Hemoglobin Oxygen Therapeutics LLC, Hemotek Medical Inc., NuvOx Pharma LLC, Omniox, Inc., and VirTech Bio Inc.

More generally, Diffusion's industry is highly competitive and subject to rapid and significant change. Potential competitors in the United States are numerous and include major pharmaceutical and specialty pharmaceutical companies, smaller biopharmaceutical companies, research universities, and others. The biopharmaceutical and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing, and marketing of health care products competitive with those that we are developing. Many of Diffusion's competitors have longer operating histories, greater name recognition, substantially greater financial resources, and larger research and development staffs than we do, as well as substantially greater experience than us in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. In addition, a significant amount of research is carried out at academic and government institutions. These institutions are aware of the commercial value of their findings and are aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed. One or more of these companies or other entities may have one or more products under development that would be competitive with Diffusion's current or future product candidates.

Sales and Marketing

Diffusion currently has no marketed products and, accordingly, currently has no sales or marketing personnel.

Government Regulation

Pharmaceutical product candidates are highly regulated by governmental authorities in the U.S. and other countries at the federal, state, and local levels. These regulations are numerous and extensive in their scope, relating to, among other things, the research and development, manufacture, storage, quality control and testing, approval, labeling and packaging, promotion, marketing, and advertising, distribution, post-approval monitoring and reporting, export and import, and record keeping of pharmaceutical products.

The FDA Drug Approval Process

Generally, before a new pharmaceutical product can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each applicable regulatory authority, submitted for review, and approved by the competent regulatory authority. In the United States, the competent regulatory authority is the FDA, which, pursuant to the FDC Act, is responsible for the review and approval of all data required to support a license to commercially market pharmaceutical products.

The process of obtaining regulatory approvals and the subsequent compliance with FDA regulations requires the expenditure of substantial time and financial resources and failure to comply with the applicable requirements at any time during the product development process, approval process, or, if approved, following approval may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties, any of which could have a material adverse effect on Diffusion's business, financial position, or results of operations.

Process Overview

The FDA drug approval process generally involves the following steps:

- completion of extensive preclinical laboratory studies, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an investigational new drug ("IND") application, which must become effective before clinical trials involving human subjects or patients may begin;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP requirements, and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication, including approval by an IRB or independent ethics committee before each trial may be initiated;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA as to whether it will accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- a potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic or drug in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources and satisfaction of FDA pre-market approval requirements typically takes many years, though the actual time required may vary substantially based upon the type, complexity, and novelty of the applicable product or indication to be treated. We cannot be certain that any approvals for any product candidates we attempt to develop in the future will be granted on a timely basis or at all.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the drug. The results of preclinical testing are submitted to the FDA as part of an IND along with other information related to the drug, including information regarding its chemical make-up, manufacturing process, and quality controls, as well as a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical Trials

Following completion of preclinical studies and the submission on an IND to the FDA, a 30-day waiting period is required. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of an investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. These trials must be conducted in compliance with federal regulations as well as GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors. Each trial is conducted under a protocol detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap, especially in certain indications such as cancer.

- Phase 1 - In Phase 1 trials, an investigational new drug is introduced into healthy human subjects and is evaluated to assess pharmacological actions, side effects associated with increasing doses and, in certain cases, early evidence on efficacy.

- **Phase 2** - In Phase 2 trials, the drug is introduced to a limited patient population in a particular indication to determine metabolism, pharmacokinetics, the effectiveness of the drug for the indication, dosage tolerance and optimum dosage, and to identify potential adverse effects and safety risks.
- **Phase 3** - In Phase 3 trials, if a drug has demonstrated evidence of effectiveness and an acceptable safety profile in prior Phase 2 trials, the drug is introduced to a larger patient population in the relevant indication to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug, and to provide adequate information for the labeling of the drug, if approved.

Not all drug development programs are required to follow the order and content of all three phases. For example, in August 2018, the FDA released a draft guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development, i.e., the first-in-human clinical trial, to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts is included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor’s initial receipt of the information.

trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk.

New Drug Application and FDA Review Process

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA containing data intended to provide substantial evidence that the drug is safe and effective in the relevant indication, and FDA approval of the NDA is required before commercial marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product’s pharmacology, chemistry, manufacturing, and controls. The cost of preparing and submitting an NDA is substantial, and the submission of most NDAs is also subject to substantial initial and ongoing fees.

The FDA has 60 days from its receipt of an NDA to determine whether the NDA will be accepted for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review subject to certain performance goals agreed upon by the FDA. Priority review can be applied in certain instances, including with respect to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process, whether standard or priority, may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or facilities at which the drug is manufactured to confirm compliance with cGMP. The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee. This advisory committee is typically a panel that includes clinicians and other experts in the relevant indication or subject matter who review and evaluate the NDA and provide a recommendation to the FDA as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

After the FDA evaluates the NDA, the clinical sites, the manufacturing facilities, and, as needed, receives a recommendation from the advisory committee, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of new information included.

FDA Approval Letter

An FDA approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy including, in certain cases, REMS as described in more detail under the heading "*Certain Other FDA Regulations – Risk Evaluation and Mitigation Strategies*" below. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Further, changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses similar procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

The Hatch-Waxman Amendments

The Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Amendments, is a 1984 U.S. federal law which established the modern system of generic drug regulation in the U.S. The Hatch-Waxman Amendments were enacted to encourage the manufacture of generic drugs by outlining the process for generic pharmaceutical manufacturers to file an abbreviated new drug application and to provide certain related protections to drug development innovators, namely a new kind of market exclusivity period and the ability to potentially extend patent life by a portion of the time a drug is under regulatory review by the FDA.

Orange Book Listing and Abbreviated New Drug Applications

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA").

An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

An ANDA applicant is required to make certain certifications to the FDA concerning any such patents listed in the Orange Book for the approved reference drug intended to confirm that the proposed generic equivalent will not infringe on any intellectual property related to the reference drug, commonly referred to as a Paragraph IV certification. The ANDA process gives the owner of the reference drug an opportunity to assert a patent infringement claim if it believes its intellectual property rights are being infringed upon following the submission of a Paragraph IV certification.

An ANDA will not be approved until all patents and non-patent exclusivity periods listed in the Orange Book for the reference drug have expired.

Patent Term Restoration and Marketing Exclusivity

Certain of Diffusion's current and future product candidates may be eligible for patent term restoration and marketing exclusivity under the Hatch-Waxman Amendment.

The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally 50% of the amount of time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for such an extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Marketing exclusivity provisions under the FDC Act can also delay the submission or the approval of certain marketing applications. The FDC Act provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example investigations related to new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. The FDC Act also provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity, meaning the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance.

During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Three-year and five-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Certain Other FDA Regulations

The Orphan Drug Act of 1983

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. For example, we previously announced that Diffusion's product candidate TSC was granted orphan drug designation by the FDA for the treatment of GBM and metastatic brain cancer in July 2011 and in December 2012, respectively. However, orphan drug designation on its own does not convey any advantage in or shorten the duration of the regulatory review and approval process but may result in certain financial and marketing incentives if approved.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because health care professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite Diffusion's orphan exclusivity. Orphan drug exclusivity could also block the approval of one of Diffusion's products for seven years if a competitor obtains approval before we do for the same drug and same indication, as defined by the FDA, for which we are seeking approval, or if Diffusion's product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the E.U. has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting. Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval for such drug.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Rare Pediatric Disease Priority Review Voucher Program

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For purposes of this program, a “rare pediatric disease” is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare diseases or conditions within the meaning of the Orphan Drug Act. On December 27, 2020, the Rare Pediatric Disease Priority Review Voucher Program was extended. Under the current statutory sunset provisions, after September 30, 2024, FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, FDA may not award any Rare Pediatric Disease Priority Review Voucher.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products are required to register and disclose to the public certain clinical trial information, including information related to the product, patient population, phase of investigation, study sites, investigators, and other aspects of the trial design. Sponsors are also obligated to discuss the results of their clinical trials after completion. However, disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved as competitors may otherwise use this or other publicly-available information to gain knowledge regarding the progress of development programs and gain a competitive advantage.

Risk Evaluation and Mitigation Strategies and Other Post-Approval Requirements

As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug’s continued approval outweigh the potential risks. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Elements to assure safe use can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring requirements, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of a drug product.

Even if the FDA does not require a REMS, once an NDA is approved, a product will be subject to certain post-approval regulations. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. Adverse event reporting and the submission of periodic reports are also required following FDA approval of an NDA.

Drug Approval Process and Other Regulations Outside of the U.S.

In addition to regulations in the U.S., Diffusion is and will be subject to the regulations of other countries in which we conduct any of Diffusion's clinical trials or engage in commercial sales or other distribution of Diffusion's products, if approved. Whether or not Diffusion obtains FDA approval for conduct of a clinical trial or distribution of a product, Diffusion must obtain approval from the competent regulatory authority of any country or economic area in which we would seek to commence a clinical trial or market products. For example, conduct of the COVID Trial in Bucharest, Romania, required certain approvals from regulatory authorities in Romania and the E.U. Certain countries outside of the United States have a process similar to the FDA's IND process which requires the submission of a clinical trial application ("CTA") prior to the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, which operates similar to an IRB under U.S. regulations. Once the CTA is approved in accordance with a country's requirements, the clinical trial may proceed in the applicable country. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In particular, in the E.U. a company may submit marketing authorization applications (comparable to an NDA submission in the U.S. to the FDA) under either a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes and is optional for medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all E.U. member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this decentralized procedure, the holder of a national marketing authorization in any E.U. member state may submit an application to the remaining member states. Within ninety days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states. The E.U. also has procedures similar to those of the FDA pursuant to which a company may obtain marketing exclusivity for a product for up to 11 years and/or orphan drug designation and related exclusivity for up to ten years, as well as other expedited approval pathways available to certain drugs.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the E.U. provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Diffusion's product candidates. Historically, product candidates launched in the E.U. do not follow price structures of the U.S. and generally tend to be significantly lower.

Certain Other Legislation and Regulations

Current Healthcare Laws and Regulations

Healthcare providers, physicians, and third-party payors, including governmental payors such as Medicare and Medicaid, will play a significant role in the recommendation and prescription of any products for which we obtain marketing approval. Diffusion's future arrangements with third party payors, healthcare providers, and physicians may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Diffusion markets, sells, and distributes any drugs for which Diffusion obtains marketing approval.

These laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, and other federal, state, and local regulations and legislation impacting the pharmaceutical and biopharmaceutical industries, including but not limited to those described below.

- [Health Insurance Portability and Accountability Act](#) - HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or falsifying, concealing, or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. HIPAA, as amended by as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state Attorneys General new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions.
- [Affordable Care Act](#) - The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended (collectively, “ACA”) was enacted in March 2010 and included measures intended to significantly change the way healthcare is financed in the U.S. by both governmental and private insurers which have and may continue to impact the pharmaceutical and biopharmaceutical industries, including expanded Medicare and Medicaid benefits, expansion of healthcare fraud and abuse laws, establishment of the Centers for Medicare & Medicaid Services, annual reporting requirements for manufacturers and distributors. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. In addition, subsequent legislation, including the Budget Control Act of 2011, American Taxpayer Relief Act of 2012, and Coronavirus Aid, Relief, and Economic Security Act of 2020, has limited and supplemented various provisions of the ACA. While Diffusion cannot predict what effect further changes to the ACA would have on Diffusion’s business, the ACA is likely to continue to impact the regulatory regime to which Diffusion is subject for the foreseeable future, and Diffusion cannot predict the ultimate content, timing, or effect of any healthcare reform legislation or the impact of potential legislation on it.
- [21st Century Cures Act](#) - The 21st Century Cures Act, signed into law in December 2016, provided for a wide range of reforms to Diffusion’s industry, such as broadening the types of data required to support drug approval, extending protections from genetic competition, accelerating approval of breakthrough therapies, expanding the orphan drug product and compassionate use programs, and clarifying how manufacturers communicate about their products.
- [Anti-Kickback Laws](#) - The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer, or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug or any other good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.
- [False Claims Laws](#) - The federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label.

- Medicare Prescription Drug, Improvement, and Modernization Act - The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 imposes requirements on the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans, but plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any reduction in payment that results from these or similar regulations may result in a similar reduction in payments from non-governmental payors.
- The Physician Payments Sunshine Act - The Physician Payments Sunshine Act, enacted as part of the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, for certain payments and “transfers of value” provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- American Rescue Plan Act of 2021 and Inflation Reduction Act of 2022 - Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s AMP, beginning January 1, 2024. Most recently, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.
- State, Local, and Non-U.S. Legislation and Regulations - In addition, to the legislation summarized above, Diffusion may also be subject now or in the future to analogous state, local, and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. Such laws are enforced by various state agencies and through private actions. For example, some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. Certain state and foreign laws also govern the privacy and security of health information in some circumstances and these data privacy and security laws may differ from both HIPAA and each other in significant ways, which would potentially increase Diffusion’s compliance burden.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. If Diffusion’s operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, Diffusion may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight, and reporting obligations if Diffusion becomes subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of Diffusion’s operations.

Future Healthcare Laws and Regulations

In the United States and foreign jurisdictions, there have been a number of proposed changes regarding the healthcare system and its regulation that could prevent or delay marketing approval of Diffusion's product candidates, restrict or regulate post-approval activities, and affect Diffusion's ability to profitably sell any product candidates for which Diffusion obtains marketing approval. Diffusion expects that further implementation of current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that Diffusion, or any strategic collaborators, may receive for any approved products. Further, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries, presidential executive orders and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

For example, in July 2021, the Biden administration released an executive order with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

U.S. Environmental, Health, and Safety Laws

Diffusion is subject to numerous environmental, health, and safety laws and regulations. From time to time and in the future, Diffusion's operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if Diffusion contracts with third parties for the disposal of these materials and waste products, Diffusion cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of Diffusion's hazardous materials, Diffusion could be held liable for any resulting damages, and any liability could exceed Diffusion's resources. Diffusion also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

In addition, Diffusion may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. Current or future environmental laws and regulations may impair Diffusion's research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Public Company Status

As a public company, Diffusion incurs significant legal, accounting and other expenses to comply with the reporting requirements of the Exchange Act and applicable requirements of SOX and the Dodd-Frank Act, as well as rules and regulations subsequently implemented by the SEC and Nasdaq, including the establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices and required filing of annual, quarterly and current reports with respect to Diffusion's business and operating results. These requirements increase Diffusion's legal and financial compliance costs and make some activities more time-consuming and costly. In addition, Diffusion's management and other personnel devote significant time and attention to these public company requirements.

Diffusion's People and Human Capital Resources

As of December 31, 2022, we had 13 full-time employees, down from 16 employees as of December 31, 2021. On February 16, 2023, in connection with Diffusion's ongoing strategic review process and efforts to utilize and preserve assets in a manner that maximizes value for its stockholders, Diffusion we committed to a reduction in force that impacted six of Diffusion's employees and, as of the date hereof, we have six full-time employees.

Diversity and Inclusion

Diffusion believes that an inclusive culture is required to understand and develop products that benefit all patients. By embracing differences, Diffusion aims to foster an environment of respect and trust in an effort to facilitate creativity, spark passion, and help us achieve better outcomes for all those who work at and with Diffusion. Diffusion is committed to creating and maintaining a workplace free from discrimination or harassment, including on the basis of any class protected by applicable law, and Diffusion's recruitment, hiring, development, training, compensation, and advancement practices are based on qualifications, performance, skills, and experience without regard to gender, race, or ethnicity. Diffusion's management team and employees are expected to exhibit and promote honest, ethical, and respectful conduct in the workplace, including adhering to the standards for appropriate behavior set forth in Diffusion's code of conduct.

Compensation and Benefits

Diffusion operates in a highly competitive environment for human capital, particularly as Diffusion seeks to attract and retain talent with relevant experience in the biotechnology and pharmaceutical sectors. Therefore, Diffusion strives to provide a total rewards package to Diffusion's employees that is competitive with Diffusion's peer companies, currently including competitive pay, a comprehensive healthcare benefits package (including an 80% employer contribution to family medical coverage), 25 days of paid leave, a company-sponsored 401(k) savings plan, short-term and long-term disability, and other benefits, as well as remote working and flexible work schedules. Diffusion also offers every full-time employee the benefit of equity ownership in Diffusion through stock option grants. Diffusion believes these grants both help promote alignment between Diffusion's employees and Diffusion's stockholders and provide retention benefits, as the awards generally vest over a three-year period.

Diffusion does not have any employees that are represented by a labor union or that have entered into a collective bargaining agreement with Diffusion.

Safety and Wellness

Diffusion believes that health matters to everyone, and the safety health, and wellness of Diffusion's employees is one of Diffusion's top priorities. Diffusion is committed to developing and fostering a work environment that is safe, professional, and promotes teamwork, diversity, and trust in order to afford all of Diffusion's employees the opportunity to contribute to the best of their abilities. In recent years, Diffusion has taken certain measures and responded to changes in Diffusion's operational needs, including actions designed to further promote a safe work environment for Diffusion's employees, including investing in technology solutions to support increased work-from-home capabilities.

Employee Development and Training

Diffusion's employees are encouraged to attend scientific, clinical, technological, and other relevant meetings and conferences and Diffusion strives to provide employees access to a broad set of internal resources intended to help them be successful, including a variety of training and educational materials. Diffusion has also implemented a comprehensive employee evaluation program tied to the achievement of individual, team, and company goals to help further support, retain, and develop Diffusion's people and further promote alignment of interests between Diffusion's employees and Diffusion's stockholders.

Directors and Executive Officers

The information set forth in "Diffusion Executive Compensation" of this proxy statement/prospectus/information statement is incorporated herein by reference.

Other Information About Diffusion

Diffusion was originally incorporated under the laws of the State of Nevada on January 10, 1995 and reincorporated under the laws of the State of Delaware on June 18, 2015 under the name, "RestorGenex Corporation." On January 8, 2016, Diffusion completed the merger of its wholly owned subsidiary with and into Diffusion LLC, which was treated as a "reverse acquisition" under GAAP pursuant to which Diffusion LLC's historical results of operations replaced the Company's for all periods prior to the merger. Immediately following the closing of the merger, Diffusion changed its name from "RestorGenex Corporation" to "Diffusion Pharmaceuticals Inc."

Diffusion's principal corporate office is located at 300 East Main Street, Suite 201, Charlottesville, Virginia 22902, and its telephone number is (434) 220-0718. Diffusion's website, www.diffusionpharma.com, including the Investor Relations section, investors.diffusionpharma.com, and its social media channels – Facebook (www.facebook.com/diffusionpharmaceuticalsinc/), Twitter (www.twitter.com/diffusionpharma) and LinkedIn (<https://www.linkedin.com/company/diffusion-pharmaceuticals/>) – contain a significant amount of information about the company. However, the information included on Diffusion's website and available through its social media channels is not incorporated by reference into, and should not be considered part of this filing.

Available Information

Diffusion makes available on or through its website certain reports that it files with or furnishes to the SEC in accordance with Exchange Act. These include Diffusion's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, as well as any amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. Diffusion makes this information available free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. The SEC also maintains a website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding Diffusion and other issuers that file electronically with the SEC. Diffusion also makes available, free of charge and through its website, the charters of the committees of the Board, its Corporate Governance Guidelines, and its Code of Business Conduct and Ethics.

Legal Proceedings

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, the former Chief Executive Officer of Diffusion's legal predecessor under the caption Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys' fees and costs. On December 30, 2014, Diffusion filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to Diffusion's petition to compel arbitration and a motion to stay the action. After a related hearing on April 14, 2015, the court granted Diffusion's petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. On November 19, 2018 at an Order to Show Cause Re Dismissal Hearing, the court found sufficient grounds not to dismiss the case and an arbitration hearing was scheduled, originally for November 2020 but later postponed due to the COVID-19 pandemic and related restrictions on gatherings in the State of California. In addition, following the November 2018 hearing, an automatic stay was placed on the arbitration in connection with the plaintiff filing for personal bankruptcy protection. On October 22, 2021, following a determination by the bankruptcy trustee not to pursue the claims and release them back to the plaintiff, the parties entered into a stipulation to abandon arbitration and return the matter to state court. A case management conference was held on February 23, 2022 at which an initial trial date of May 24, 2023 was set, and the parties have agreed to stipulate to mediation in advance of the trial. On October 20, 2022, the parties filed a joint stipulation to continue the trial and certain deadlines related to the mediation in order to allow plaintiff's counsel to continue to seek treatment for an ongoing medical issue. On November 1, 2022, based on the parties joint stipulation, the court entered an order continuing the trial date to October 25, 2023.

Diffusion believes the claims in this matter are without merit and is defending itself vigorously. However, at this stage, Diffusion is unable to predict the outcome and possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on Diffusion's financial position. Depending on the outcome or resolution of this matter, it could have a material effect on Diffusion's consolidated financial position, results of operations and cash flows.

In addition, from time to time, Diffusion is subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business, which may include employment matters, breach of contract disputes and stockholder litigation. Such actions and proceedings are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. Diffusion records a liability in its consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, when Diffusion has assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, Diffusion records the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. Diffusion discloses a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that a material loss may have been incurred. In the opinion of management, as of the date hereof, the amount of liability, if any, with respect to these matters, individually or in the aggregate, will not materially affect Diffusion's consolidated results of operations, financial position or cash flows.

EIP BUSINESS

Unless the context otherwise requires, all references in this section to “we,” “our,” “us,” “EIP” or “EIP Pharma” refer to the business of EIP Pharma, Inc. prior to the consummation of the Merger.

Overview

We are a clinical stage CNS therapeutics company that is developing treatments for acute and chronic neurodegenerative diseases, such as DLB, and other neurologic indications. In DLB, for which there are currently no approved therapies and no disease-modifying drugs in Phase 3 clinical trials, we believe that we are one of the leaders in the industry, as we are the only company of which we are aware with an asset that, in that disease, has shown statistically significant positive effects compared to placebo in a Phase 2a clinical trial and is about to enter late-stage (Phase 2b) clinical evaluation. Our novel approach focuses on reducing the impact of inflammation in the brain, or neuroinflammation, which we believe is a key factor in the manifestation of neurodegenerative disease. Chronic activation of the enzyme, p38 mitogen-activated protein kinase (“MAPK”) alpha (“p38 α ”) in the neurons (nerve cells) within the brains of people with neurodegenerative diseases is believed to impair how neurons communicate through synapses (the connections between neurons). This impairment, termed synaptic dysfunction, leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in neuronal loss that leads to devastating disabilities, institutionalization and, ultimately, death. We believe that inhibiting p38 α in the brain, by interfering with key pathogenic drivers of disease, has the potential to improve cognitive and motor function observed in early-stage neurodegenerative diseases. We also believe it is possible to modify the course of these diseases by delaying permanent synaptic dysfunction and neuron death.

We are developing an oral therapy, neflamapimod, that penetrates the blood-brain barrier and inhibits activity of p38 α in the neuron. Based on preclinical and clinical work to date, we believe if neflamapimod is given in the early stages of neurodegenerative diseases, it may reverse synaptic dysfunction and improve neuron health. In preclinical studies, neflamapimod has been shown to reverse the neurodegenerative process in the basal forebrain cholinergic system, the specific region of the brain that is the site of the major pathology in DLB. We have obtained positive Phase 2a clinical data in DLB, specifically, statistically significant improvement compared to placebo on measures of dementia severity and functional mobility (walking ability). In addition, we previously obtained Phase 2 clinical data in AD that provides support by demonstrating blood-brain-barrier penetration, target engagement, and identifying dose-response.

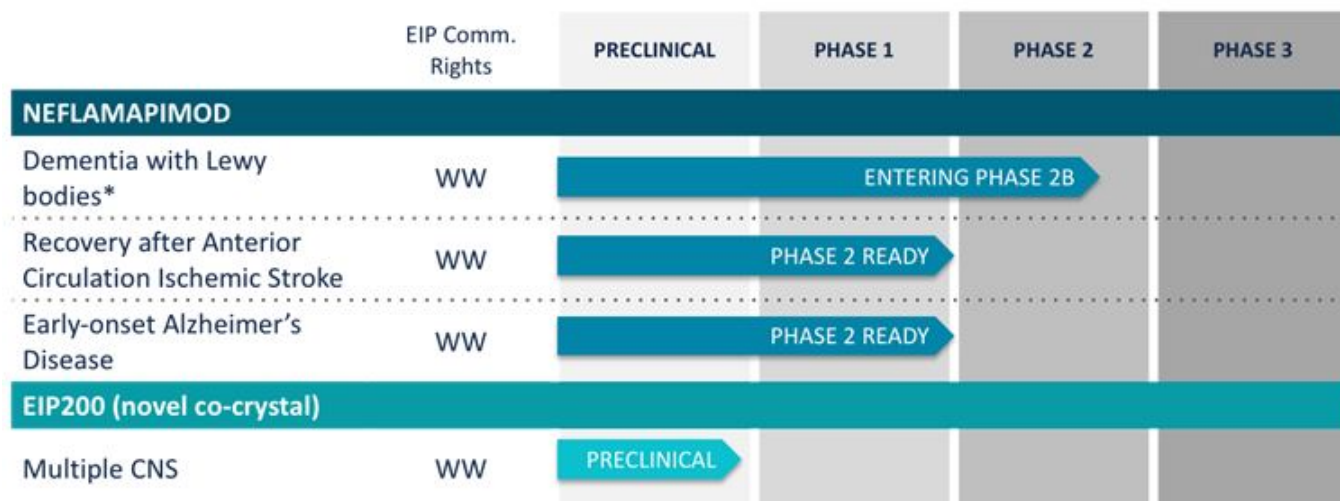
There are an estimated 700,000 individuals with DLB in each of the United States and the EU. The disease in afflicted persons progresses and severely impacts not only their daily lives but that of their caregivers. To date, the management of DLB, involves treating certain cognitive and motor symptoms, with modest albeit transient improvement. No approaches have been shown to clinically slow neuronal loss or prevent cognitive decline, and there are no approved therapies for treating the underlying disease’s process. Our approach is based on understanding the mechanism by which neuroinflammation leads to the initiation of the neurodegenerative process through synaptic dysfunction. In major neurodegenerative diseases, the end result of the process is neuronal loss. Before neuronal loss commences, disease progression in major neurodegenerative disorders, including DLB, initially involves a protracted period of functional loss, particularly with respect to the synapses. We seek to target the molecular mechanisms within neurons that lead to synaptic dysfunction. We believe that successful treatment of synaptic dysfunction will provide patients with an improvement in cognition and motor function in the first few weeks or months after treatment initiation, followed by a slowing of neuronal loss and associated disease progression (i.e., further cognitive and motor function decline). Importantly, the clinical symptoms in DLB are most directly linked to synaptic dysfunction in cholinergic neurons (neurons producing the neurotransmitter acetylcholine) in a part of the brain named the basal forebrain, while scientific and preclinical data with neflamapimod support the notion that neflamapimod treats the molecular mechanisms underlying dysfunction and degeneration of such basal forebrain cholinergic neurons.

Neflamapimod has been evaluated in more than 300 healthy volunteers and patients, including in 149 subjects in Phase 2 clinical trials in either DLB or AD. We have obtained positive Phase 2a clinical data in DLB. Specifically, in a 91-subject, 16-week placebo-controlled Phase 2a clinical trial in DLB, in the all-subject analysis neflamapimod demonstrated improvement vs. placebo in dementia severity (evaluated by the Clinical Dementia Rating, CDR, Sum of Boxes test, p=0.023 vs. placebo) and motor function (evaluated by the Timed up and Go (“TUG”) test, TUG p=0.044 vs. placebo). In secondary analysis, at highest dose (40m three times daily, (“TID”)), significant improvement vs. placebo was also seen on a cognitive test battery. The Phase 2 clinical data in AD provides support through demonstrating blood-brain-barrier penetration, target engagement in the brain, and understanding of dose-response.

Our next step in the clinical development of neflamapimod is the conduct of a Phase 2b placebo-controlled 160-subject clinical trial intended to confirm the Phase 2a results and provide the data necessary to finalize design of a Phase 3 clinical trial, the general framework of which has been agreed upon with the FDA. The Phase 2b trial will be fully funded by an awarded grant from the NIA and is planned to be initiated by the end of the second quarter of 2023, with data-readout in the second half of 2024.

In addition to its potential to treat DLB, we believe the benefit of targeting neuroinflammation-induced synaptic dysfunction in the basal forebrain cholinergic system can be applied to other neurologic indications including as treatment promoting recovery in the three months after ischemic stroke and as a disease-modifying treatment for Early Onset Alzheimer’s Disease (“EOAD”). The scientific rationale for evaluating neflamapimod to promote recovery after stroke is predicated on the basal forebrain cholinergic (“BFC”) system playing a critical role in recovery, particularly motor function, after ischemic stroke. Impaired activity of that system by residual inflammation limits the extent of recovery that otherwise occurs in the weeks and months after an acute stroke event. Through the same mechanisms as in DLB, neflamapimod would be predicted to reverse suppression of basal forebrain cholinergic function, leading to improved recovery of motor activities. As there are overlapping disease mechanisms, the scientific rationale for EOAD is the same as that for DLB.

Set forth below is a table presenting our clinical pipeline:



*Received FDA Fast Track designation

In 2012, we entered into an Option and License Agreement with Vertex and subsequently acquired an exclusive license from Vertex in 2014 to develop and commercialize neflamapimod for the treatment of AD and other neurodegenerative diseases. We have made a number of discoveries related to our lead product candidate, neflamapimod, which have enabled us to build a wholly owned intellectual property (“IP”) portfolio, which provides protection to 2032 (methods of treating patients suffering from AD) and 2035 (uses of neflamapimod for improving cognition). In addition, we have a patent on the formulation of neflamapimod that is protected through 2039.

Our Strengths

We believe that the following competitive strengths will allow us to execute on our mission to develop and commercialize disease modifying innovative drug treatments for patients who suffer from DLB and other neurodegenerative diseases:

- Our approach to neurodegenerative diseases is highly differentiated and has the potential to be the first to market specific drug therapy for DLB. Our approach focuses on reducing the impact of neuroinflammation, which is directly linked with the initiation of the neurodegenerative process through synaptic dysfunction. Our technology targets the molecular mechanisms within neurons that lead to synaptic dysfunction, thereby both improving cognitive function and slowing down the process that leads to neuronal loss. Currently, there are no approved therapies for DLB and there is limited drug development in this area, with neflamapimod being, to our knowledge, the only disease-modifying approach that has demonstrated significant positive effects on clinically outcome measures in a clinical trial in DLB.
- Our drug has the potential to meet a significant unmet medical need and achieve substantial commercial return. We believe that neflamapimod can address the high unmet medical need with respect to both the cognitive and motor aspects of DLB. DLB is the second most common neurodegenerative dementia, with an estimated 700,000 individuals with the disease in each of the United States and EU. Further, the commercialization model focuses on a neurologist call point, and high pricing leverage due to the high caregiver burden and health care costs associated with DLB.
- The path to approval in DLB does not depend on having to demonstrate an effect on disease progression. A major challenge in developing effective drug treatments for chronic neurodegenerative diseases, particularly AD, has been that approaches to date do not show improvement in disease outcomes in Phase 2 clinical trials (i.e., trials of less than six-month duration). As a result, demonstration of clinical efficacy depends on clinical trial duration of at least 12 to 18 months and large subject numbers (~1,000 or more), effectively requiring Phase 3 trials designed to show an effect of slowing disease progression relative to placebo treatment. In early-stage DLB, because there is less extensive neuronal loss and fixed deficits compared to AD, there is the potential to reverse disease progression and improve disease outcomes in Phase 2 clinical trials. Moreover, neflamapimod has shown the ability to reverse disease progression and restore function in preclinical studies and has shown improvement vs. placebo on clinically meaningful outcomes in a 16-week Phase 2a clinical trial. If the Phase 2a results are confirmed in the upcoming Phase 2b trial (the placebo-controlled portion of which will also be of 16 weeks duration), based on discussions we have had with the FDA, and pending confirmation in an end-of-phase 2 meeting with the FDA that we plan to have after Phase 2b, approval for neflamapimod could be obtained with the conduct of a single 24-week treatment duration Phase 3 study involving a few hundred subjects, that would have to simply replicate the results of the planned Phase 2b trial.
- **Neflamapimod has been extensively tested in animals and humans.** The safety and tolerability profile has been extensively evaluated and is well understood. Specifically, long-term toxicology studies of neflamapimod have been completed and the drug has been administered to over 300 volunteers and subjects to date, some of whom have received up to 30 times the dose we will be using in our upcoming Phase 2b clinical trial and plan to utilize in Phase 3.
- **We have assembled a highly experienced executive management team.** Our CEO, John Alam, MD, is a biotech industry veteran with 30 years' experience and is an industry leader in translational medicine. He has a proven track record of creating value through clinical development success, including having played major roles during the clinical development of five innovative drugs that are now on the market, and is an emerging drug development leader in neurodegenerative diseases, including having been the global head of all R&D activities directed towards neurodegenerative diseases at Sanofi, a top ten global pharmaceutical company. Dr. Alam also has direct experience with neflamapimod from his time at Vertex, where he was EVP, Medicines Development and Chief Medical Officer. Dr. Alam, also led the clinical development of Biogen's first approved drug for the treatment of multiple sclerosis, Avonex. Our Chairwoman of the Board, Dr. Sylvie Grégoire, is also an industry veteran with 30 years' experience who previously held executive leadership posts in several multinational life sciences firms. Dr. Grégoire has extensive experience with corporate governance and board operations and is currently also on the board of directors at of two public life sciences companies, Novo Nordisk A/S (NYSE: NVO) and PerkinElmer, Inc. (NYSE: PKI), and one private company, F2G; and she previously was chair of Corvidia Therapeutics (acquired by Novo Nordisk), and member of the board of directors of ViFor Pharma (acquired by CSL) and Cubist Pharmaceuticals (acquired by Merck). EIP's Chief Financial Officer, William Tanner, through his more than 20 years' experience as a healthcare research analyst at well recognized investment banks, has expertise and relevant industry experience. Moreover, we benefit from the significant pharmaceutical development experience of our management team members, several of whom have worked on neflamapimod in the past at Vertex and are well acquainted with the unique properties of the compound for application in our target indications.

- **To provide a strong scientific underpinning for the neflamapimod program, we have surrounded ourselves with thought leaders in the fields of cell biology, intracellular signal transduction, neurotherapeutics, and translational neuroscience.** Our Scientific Advisory Board (“SAB”) is chaired by Dr. Ole Isacson, who serves as Professor of Neurology at Harvard Medical School and is a Founding Director of Neuroregeneration Research Institute at McLean Hospital. Other members of our SAB include Dr. Lewis Cantley, who serves as the Director of the Sandra and Edward Meyer Cancer Center and as Professor of Cancer Biology in Medicine at Weill Cornell Medical College; Dr. Jeffrey Cummings, Director of the Center for Neurodegeneration and Translational Neuroscience at the Cleveland Clinic, Director Emeritus of the Cleveland Clinic Lou Ruvo Center for Brain Health and Professor at the Cleveland Clinic Lerner College of Medicine; and Dr. Heidi McBride, Canada Research Chair in Mitochondrial Cell Biology and as Professor in the Department of Neurology and Neurosurgery at McGill University.

Our Strategy

Our mission is to develop and commercialize innovative medicines that change the course of the disease of patients who suffer from neurodegenerative diseases.

The key elements of our strategy are:

- Advance clinical development of neflamapimod for treatment of DLB with a focus on moving the program through to Phase 3 initiation in the first half of 2025. We plan to initiate a Phase 2b clinical trial with neflamapimod in DLB by the end of the second quarter of 2023 and anticipate completing enrollment in the first half of 2024. The efficacy data, which would come at the end of the four-month placebo-controlled portion of the trial, are expected in the second half of 2024. With those results in hand, we plan to meet with the FDA in an end-of-phase 2 meeting to finalize the design of a single Phase 3 clinical trial, which we are targeting to initiate in the first half of 2025.
- Advance clinical development of neflamapimod for other disease indications. Neflamapimod’s mechanism of action with respect to treating cholinergic dysfunction and degeneration provides opportunities to advance our drug in a range of neurologic disorders in addition to DLB. Our anticipated second indication is as a three-month treatment following ischemic stroke to promote neurologic recovery, particularly of motor function. A potential third indication is as disease-modifying treatment for EOAD. In addition, we believe there is strong scientific basis for evaluating neflamapimod in combination with anti-amyloid beta directed approaches in Late Onset AD (“LOAD”).
- Commercialize neflamapimod ourselves and/or in collaboration with one or more partners. If neflamapimod receives regulatory approval, we intend to retain significant commercial rights in North America and Europe. In the future, we may seek partners to commercialize our products in other regions.
- Expand our pipeline through in-licensing and acquisitions. We intend to leverage our expertise in drug development and business development, as well as our understanding of translational neuroscience with respect to synaptic dysfunction, to evaluate product candidates that are complementary to neflamapimod in our pursuit of novel therapies for DLB, AD and other neurodegenerative diseases.

Our Approach

Our approach is based on an understanding of the mechanism by which neuroinflammation leads to the initiation and establishment of the neurodegenerative process through dysfunction of synapses (the interconnections between neurons), i.e., synaptic dysfunction. Treating synaptic dysfunction has emerged as a major therapeutic objective to address progression of neurodegenerative diseases, particularly in the early stages prior to the onset of significant cell death. Importantly, in animal models, while neurodegeneration is irreversible, synaptic dysfunction is reversible. In addition, even in animal models of rapidly progressive neurodegeneration, interventions that reverse synaptic dysfunction both improve function and “arrest” the neurodegenerative process. Thus, therapeutic interventions that target synaptic dysfunction have the potential to both reverse and slow disease progression in the early stages of neurodegenerative dementias.

The basal forebrain, and specifically nerve cells producing the neurotransmitter acetylcholine (i.e., “cholinergic neurons”), play critical roles in controlling and optimizing a wide range of cognitive, motor, and visual tasks. Synaptic dysfunction in the basal forebrain cholinergic system is the primary pathogenic driver of disease expression and progression DLB. Basal forebrain cholinergic dysfunction also plays a major role in disease progression in the early stages of AD, and basal forebrain cholinergic function is rate limiting for optimal recovery after ischemic stroke.

In collaborative work conducted with the New York University Langone Medical Center, we have demonstrated that neflamapimod specifically targets the specific molecular mechanisms underlying basal forebrain cholinergic dysfunction, and eventually degeneration, and, as discussed in subsequent sections, can successfully reverse disease progression in animals with basal forebrain cholinergic degeneration.

Neflamapimod in Dementia with Lewy Bodies (DLB)

Unmet Medical Need

DLB is the second most common neurodegenerative dementia (after AD), representing 10-20% of the dementia population. The Lewy Body Dementia Association estimates that there are 1.4 million individuals in the United States affected with Lewy body dementia, which includes both Parkinson’s disease dementia (“PDD”) and non-Parkinson’s DLB. As non-Parkinson’s DLB and PDD are prevalent in the United States at a 1:1 ratio, there are approximately 700,000 individuals with DLB in the United States. Furthermore, the prevalence in European countries is similar to that in the United States, and so we believe there are also approximately 700,000 individuals with DLB in the EU.

DLB is characterized by progressive dementia and fluctuating cognition (particularly deficits in attention), visual hallucination, motor dysfunction (disturbances in gait and balance) and sleep disturbances. With respect to life expectancy, in a large cohort of DLB and AD cases (251 DLB, 222 AD), after controlling for age at diagnosis, comorbidity, and antipsychotic prescribing, the survival for DLB was shorter compared to AD, with a median (average) survival of less than four years with DLB (3.3 years for males and 4.0 for females), while that for AD was nearly seven years (6.7 years for males and 7.0 years for females). Antecedent to death, the time progression to severe dementia is also shorter by nearly two years with DLB compared to AD.

Separate from survival and progression to severe disease, even in the mild-to-moderate stages, with deficits occurring in both cognitive and motor function, the disease burden with respect to quality of life and caregiver burden, is greater in DLB than in AD.

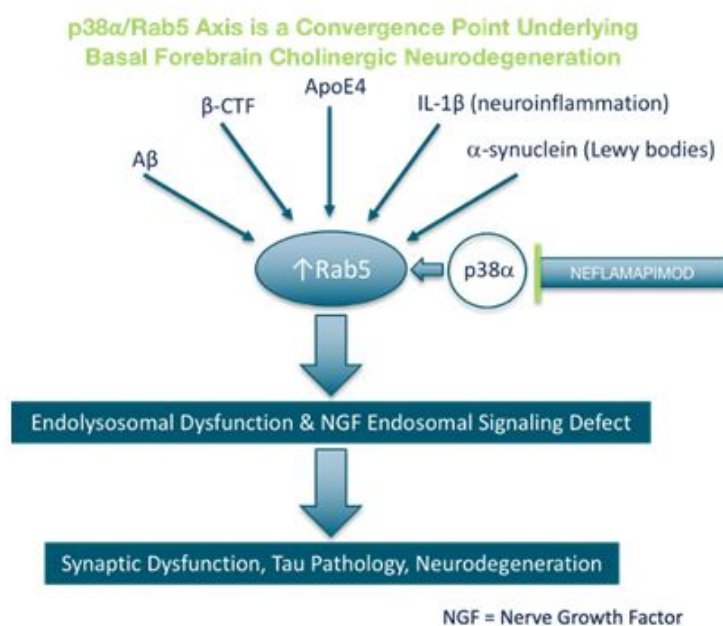
Furthermore, patients with DLB are more frequently admitted to general hospitals and utilize inpatient care to a substantially higher degree than do those with AD or the general elderly population. Most importantly, in a large prospective study, mild dementia patients with DLB were admitted to a nursing home after only a median of 1.8 years from presentation and diagnosis, nearly two years shorter than the 3.7 years in the AD group.

There are no disease-modifying treatments available for DLB, so management of DLB currently focuses on relief of symptoms, including its cognitive and parkinsonian (e.g., tremor) manifestations. Though not approved for DLB, cholinesterase inhibitors are used in its management, with some limited, though transient, improvement in cognition and a reduction in the frequency and severity of visual hallucinations. However, despite treatment with cholinesterase inhibitors, the cognitive and functional impairments progress rapidly, caregiver burden remains high, and new treatments are needed for these patients. With respect to the motor component of DLB, dopaminergic medications (e.g., carbidopa/levodopa) work less well in DLB compared to in Parkinson’s disease (“PD”) and patients with DLB generally have a limited response to these medications, which are in any case poorly tolerated in this patient population; a reason for the poor response is that DLB is primarily a disease of the cholinergic system, rather than the dopaminergic system.

Scientific Rationale

Recent evidence indicates that the primary pathology in DLB is in the basal forebrain cholinergic system, degeneration and dysfunction of which drives neurodegeneration in other regions of the brain. A series of publications from the laboratories of William Mobley at UCSD and Ralph A. Nixon at NYU Langone have defined the molecular mechanisms that lead to neurodegeneration of cholinergic neurons. As shown in figure below, the cholinergic degeneration is believed to result from inflammation and various aggregated proteins that lead to aberrant activation of the protein Rab5, a master regulator of endocytosis and endosomal trafficking, further leading to impaired retrograde axonal transport and a block in nerve growth factor (“NGF”) signaling from the synapses back to the neuronal cell body. The resulting loss of trophic support is then believed to lead to dysfunction, and, eventually, degeneration of cholinergic neurons, which are particularly vulnerable to this pathogenic process because of their very long axonal processes. In this pathogenic model for cholinergic degeneration in DLB, a key therapeutic target is Rab5. Neflamapimod was hypothesized to act on Rab5 because of scientific literature showing that the immediate target of neflamapimod, p38 α kinase, is the major activator of Rab5. Based on that hypothesis, neflamapimod was evaluated in a preclinical study in an animal model of basal forebrain cholinergic degeneration and in a clinical trial in patients with DLB, a disease in which, basal forebrain cholinergic degeneration is also prominent. The results of those studies were recently published, and the clinical and preclinical findings are summarized in the following sections.

Molecular Mechanisms Underlying Cholinergic Neurodegeneration in DLB and Point of Intervention for Neflamapimod



In distinction to AD, pure DLB (DLB in the absence of concomitant AD) has relatively limited neurodegeneration and neuronal loss in the cortical regions of the brains. Moreover, based on a range of animal and human pathology studies, the cholinergic degenerative process in the basal forebrain is believed to be reversible. The cholinergic neurons in that region of the brain do not die, rather they stop functioning and atrophy (shrink in size). However, as those neurons are still present, they can be rescued and the disease process reversed with successful pharmacological treatment, a possibility that we believe our product candidate, neflamapimod, has demonstrated in preclinical studies involving animal models (see results below). Moreover, we believe that the positive Phase 2a results in DLB described reflect a similar effect on the basal forebrain cholinergic system, with the magnitude of the treatment effect being most prominent in patients with low levels of a plasma biomarker (ptau181) that is associated with both AD co-pathology and neuronal loss in the cortex.

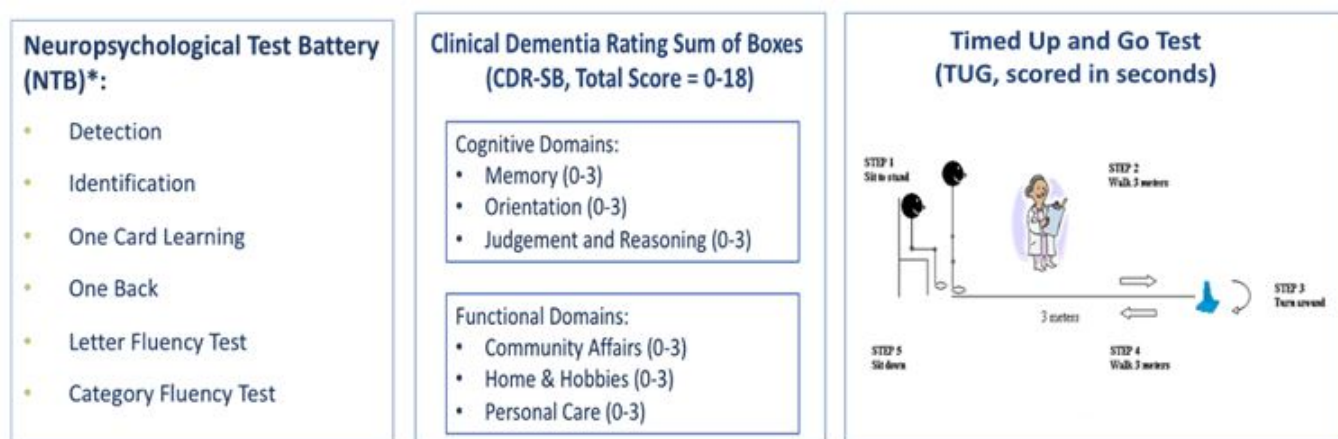
Our Phase 2a Trial in Dementia with Lewy Bodies (DLB)

AscenD-LB was a Phase 2a double-blind, placebo-controlled, 16-week treatment, exploratory clinical trial of neflamapimod in mild-to-moderate DLB conducted at 22 centers in the United States and two centers in the Netherlands. 91 subjects were enrolled between October 2019 and March 2020 and randomized to receive 40 mg neflamapimod capsules or matching placebo capsules (randomized 1:1) for 16 weeks. The dosing regimen was based on weight, with trial participants weighing less than 80 kg receiving capsules twice daily (“BID”) and those weighing greater than or equal to 80 kg receiving capsules TID. All subjects had to have already been receiving oral cholinesterase inhibitor therapy for at least three months (stable dose for greater than six weeks) and continued such therapy without dose modification during the trial.

The major clinical outcome measures were as follows:

- A six test Neuropsychological Test Battery (“NTB”). The NTB is a cognitive test battery designed to evaluate attention, executive function, and visual learning, i.e., the cognitive domains most impacted in DLB. The NTB was analyzed using a standard statistical approach by which the individual test results are normalized by using “z-scores” and the combined using equal weights into a single composite z-score. The two tests within the NTB that evaluate information processing speed (Detection and Identification tests) were also combined into an Attention composite z-score.
-
- CDR-SB. The CDR-SB is obtained through a semi-structured questionnaire given to both the caregiver and subject and is scored from 0-3 in each of three cognitive (memory, orientation, judgement and reasoning) and three functional domains (community affairs, home & hobbies, personal care)
- TUG test. The TUG test, measuring functional mobility, monitors the time in seconds that a subject takes to rise from a chair, walk three meters, turn around 180 degrees, walk back to the chair, and sit down while turning 180 degrees.

Outcome Measures in AscenD-LB Phase 2a Clinical Trial of Neflamapimod in DLB



*DLB-specific cognitive test battery designed to assess attention, executive function and visual learning
NTB composite: results of all six tests combined into single z-score
Attention composite: Detection and Identification tests combined into single z-score

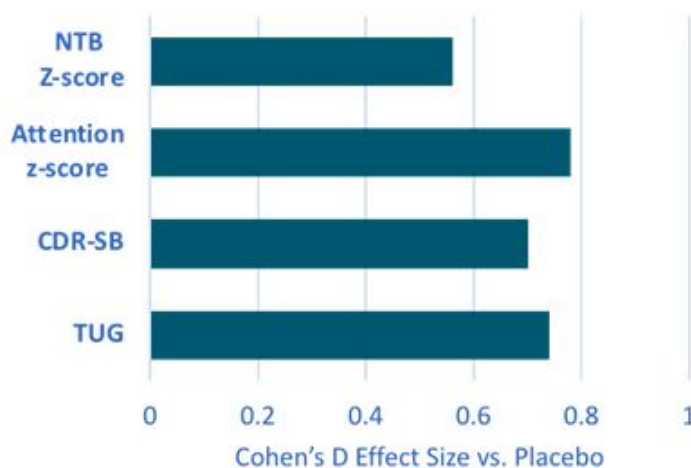
In the modified intention-to-treat population (all subjects with at least one on-treatment efficacy evaluation) analysis of the AscenD-LB trial, neflamapimod demonstrated improvement vs. placebo in dementia severity (evaluated by the gold standard Clinical Dementia Rating Sum of Boxes, CDR-SB, $p=0.023$) and functional mobility (gait or walking ability, as assessed by the Timed up and Go test, TUG $p=0.044$). In additional analyses, at highest dose (40mg TID) vs. placebo, significant improvement on NTB was evident ($p=0.049$). In addition, encouraging positive trends on the 10-item Neuropsychiatric Inventory (NPI-10) were seen; particularly with respect to visual hallucinations, where a significant reduction in frequency relative to placebo was seen. We believe, if the effects on multiple aspects of DLB, including on both cognition and gait, are confirmed in Phase 2b and 3, neflamapimod would be a transformative treatment for this serious disease.

Efficacy Results in Phase 2a Trial of Neflamapimod in DLB

Outcome Measure	Comparison of all neflamapimod (40mg BID and 40mg TID) with placebo		Comparison of neflamapimod 40mg TID with placebo	
	Drug-Placebo Difference On-Study (95% CI)	p-value	Drug-Placebo Difference On-Study (95% CI)	p-value
CDR-SB	-0.45 (-0.83,-0.06)	0.023	-0.56 (-0.96,-0.16)	0.007
NTB Composite z-score	0.04 (-0.11, 0.19)	>0.2	0.17 (0.00, 0.35)	0.049
Attention Composite z-score	0.14 (-0.06, 0.35)	0.17	0.28 (0.04, 0.51)	0.023
TUG	-1.4 (-2.7,-0.1)	0.044	-1.4 (-2.6,-0.2)	0.024

Improvement is reflected as increases in NTB, and as decreases in CDR-SB and TUG test

Post-hoc analyses of the AscenD-LB data stratified by baseline plasma ptau181 (tau protein phosphorylated at residue 181) have identified this biomarker as an enrichment strategy to further improve treatment response in subjects with DLB. These analyses were conducted because recent scientific literature has demonstrated that DLB subjects with abnormally elevated plasma ptau181 have AD associated co-pathology (specifically amyloid plaque and/or tau pathology by PET scan or cerebrospinal fluid (“CSF”) analysis). Further, compared to subjects with DLB without elevated plasma ptau181, subjects with DLB with elevated plasma ptau181 have more extensive neuronal loss (neurodegeneration) and, therefore, would be expected to be less responsive to treatment. Within the AscenD-LB trial, the subjects without elevated plasma ptau181 had a higher treatment response, compared to the response in subjects with elevated plasma ptau181, and demonstrated significant improvement in cognitive tests of Attention, the CDR-SB and the TUG test, with Cohen’s *d* treatment effect size that was greater than 0.7 for all three endpoints, indicating clinical effects that are moderate-to-large in magnitude. For comparison, in published studies in the scientific literature, the cholinesterase inhibitors have Cohen’s *d* effect size of approximately 0.3 in the treatment of AD or DLB.

Magnitude of Neflamapimod Treatment Effect vs. Placebo in Subjects with Baseline Plasma ptau181 less than 2.2 pg/mL (i.e., without biomarker evidence of AD co-pathology)*

*By convention the magnitude of a treatment is considered small when the Cohen's *d* effect size between 0.2 and, moderate when it is 0.4 to 0.8 and large when it is 0.8 or greater.

The results of the AscenD-LB trial were published in the major scientific journal Nature Communications in September 2022.

Results of Phase 2 Studies in AD

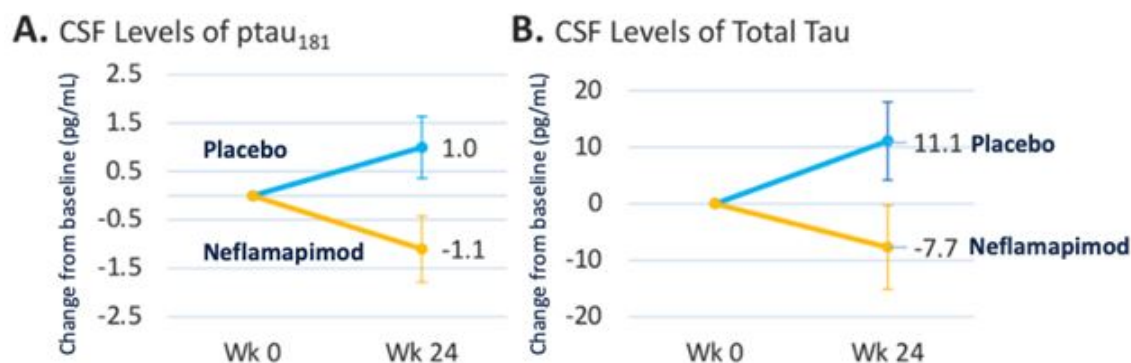
Ahead of the Phase 2a clinical trial in DLB, our clinical trials in AD provided us data around blood-barrier penetration target engagement (biological activity in the brain), and an understanding of dose-response, i.e., the completion of the steps in early clinical studies to successful CNS drug development.

Two Phase 2a studies in AD were completed in early 2017. Results from these studies demonstrated that neflamapimod is well tolerated, crosses the blood brain barrier and is pharmacologically active in the brain.

Reverse-SD was a Phase 2b clinical trial in subjects with AD. 161 subjects were enrolled at 38 sites in the Czech Republic (5 sites), Denmark (3 sites), Netherlands (3 sites), United Kingdom (11 sites) and United States (16 sites) and were randomized 1:1 to receive neflamapimod 40 mg capsules or matching placebo capsules twice daily with food for 24 weeks. Inclusion criteria were as follows: men and women aged 55 to 85 years, with CDR-Global score of 0.5 or 1.0 (i.e., with mild AD); CDR memory sub-score of at least 0.5; MMSE score of 20 to 28, inclusive; positive biomarker for AD, as defined by CSF A β 1-42 <1000 pg/mL and phospho-tau/A β 1-42 >0.024 in the Roche Elecsys® immunoassay; receiving either no AD-specific therapy or on a stable dose monotherapy (either cholinesterase inhibitor or memantine; dual therapy excluded).

Including all subjects in the analysis, there was no evident difference between the neflamapimod and placebo groups in the primary clinical efficacy endpoint, the combined change from baseline to week 24 in the z-scores of Hopkins Verbal Learning Test ("HVL") Total Recall and Delayed Recall. In the analysis of CSF biomarkers, there were statistically significant effects of neflamapimod treatment, with a reduction relative to placebo, in the change from baseline to week 24 in CSF protein levels of phosphorylated tau (p-tau181, $p=0.01$ vs. placebo) and total tau ($p=0.03$ vs. placebo), and a trend on CSF neurogranin ($p=0.07$ vs. placebo).

Because in the scientific literature tau pathology has been shown to be downstream (is a consequence) of p38 α kinase activity, the effect of neflamapimod on CSF levels of ptau181 and total tau demonstrates target engagement, i.e., these CSF results is consistent with "target engagement" within the brains of subjects. Target engagement is the industry term for the drug having the intended pharmacological effect in humans that would be expected based on its mechanism of action; in this case, that neflamapimod is inhibiting p38 α activity. Furthermore, as CSF ptau181 and CSF total tau are considered to reflect neurodegeneration and synaptic dysfunction, respectively, we believe the results also provide objective evidence of neflamapimod impacting the neurodegenerative process in patients, including specifically on synaptic dysfunction.

Effects of Neflamapimod on the Change from Baseline to Week 24 on CSF Levels of Phosphorylated Tau and Total Tau

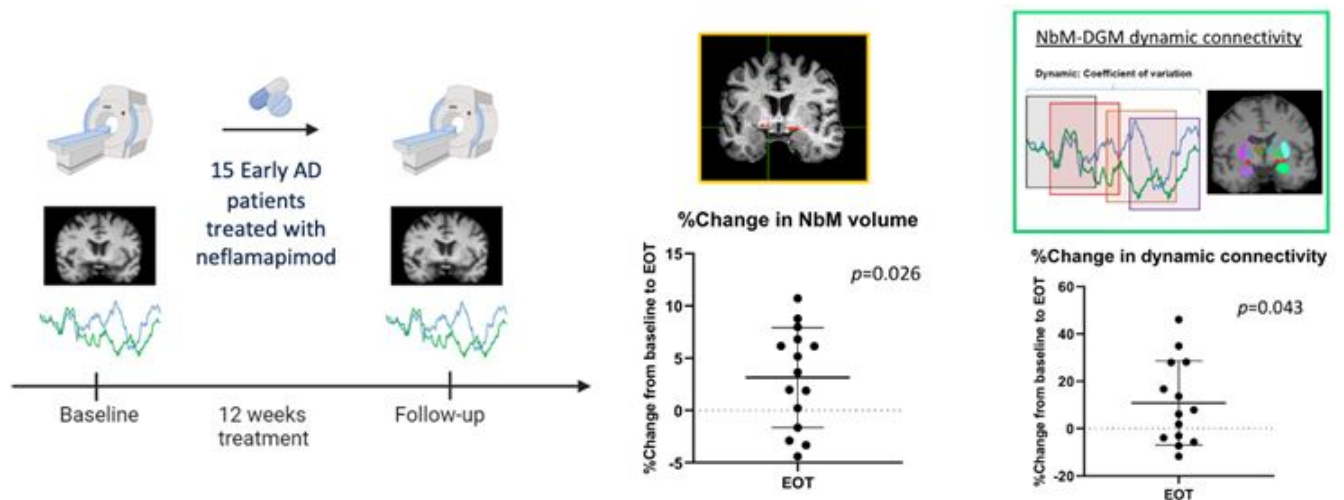
As a single dose of neflamapimod was utilized in the trial, pre-specified pharmacokinetic pharmacodynamic analyses were conducted to evaluate the results for potential dose-dependency. These analyses showed improvement, relative to the placebo group, in tests of episodic memory in neflamapimod-treated subjects with the highest (top quartile) trough plasma drug concentrations; with positive trends evident both for the primary endpoint (combined change in z-scores of HVLt total recall and delayed recall) and the major secondary endpoint of change in Wechsler Memory Scale Combined Immediate and Delayed Recall composites. This analysis provided critical dose-response information as it indicated that 40mg BID was too low a dose, but that a dose of 40mg TID would achieve therapeutically effective drug concentration levels in the blood. Moreover, combined with the CSF biomarker findings, the results suggested that neflamapimod had potential to slow disease progression in AD, and that clinical trials of longer clinical duration to evaluate that potential were warranted.

An investigator-initiated study (i.e., not sponsored and conducted by EIP Pharma) in subjects with mild AD was initiated in late 2018 at the CHU in Toulouse, France. The primary objective of this study was to assess the effects of neflamapimod on neuroinflammation compared to placebo after 12 weeks of treatment using a novel PET radiotracer, [18F]DPA-714. This novel PET radiotracer targets binding of the translocator protein that has been suggested to be specific for microglial activation. The study was originally intended to enroll 40 subjects, 20 receiving placebo and 20 receiving neflamapimod 40mg BID for 12 weeks. However, the study was interrupted by the COVID-19 pandemic, and eventually completed in early 2022, having enrolled 26 subjects. While the results have not been reported publicly or published, our understanding is that, with the enrollment numbers and greater than expected variability in the PET data, the data was inconclusive.

Results of Imaging of Basal Forebrain by MRI after Treatment with Neflamapimod

With the development and availability of analytic MRI-based techniques to evaluate potential treatment effects on the basal forebrain, the MRI images from one of the two Phase 2a studies in mild AD were reanalyzed by specialized neuroimaging group at the Amsterdam Medical Center. The goal of this exploratory analysis, which was presented at the AD/PD meeting in Gothenburg, Sweden in April 2023, was to assess the treatment effects of neflamapimod on the Nucleus basalis of Meynert (“NbM”), the largest cluster of cholinergic neurons in the basal forebrain, assessed by MRI (magnetic resonance imaging), in a previously completed Phase 2a trial in subjects with mild AD (n=15). Structural and MRI assessments had been conducted at baseline and following 12 weeks of treatment with neflamapimod. The analysis demonstrated that the NbM volume was statistically significantly higher at the end of treatment (“EOT”, mean 3.1% higher vs. baseline, p=0.026); with eight of 15 subjects having greater than 3% NbM higher volume at EOT, compared to baseline. Treatment with neflamapimod was also associated with a statistically significantly higher functional dynamic connectivity between the NbM and deep grey matter (“DGM”) at EOT (mean 11% higher vs. baseline, p=0.043); with six of 13 subjects showing a greater than 10% higher dynamic NbM-DGM connectivity at EOT, compared to baseline. We believe, the potential regression of atrophy and recovery of function in neflamapimod-treated subjects in this trial suggests a restoration of cholinergic neurons in the NbM in line with the data generated in previous preclinical studies that demonstrated neflamapimod reversed the neurodegenerative process in the basal forebrain cholinergic system.

Neflamapimod treatment was associated with increased basal forebrain volume and functional connectivity



NbM – Nucleus basalis of Meynert, largest cluster of cholinergic neurons in the basal forebrain; DGM – Deep Grey Matter

Clinical Safety Results

Adverse events seen in all Phase 2 clinical trials in both CNS and non-CNS disorders are shown in the table below. Regarding more specifically clinical trials in CNS disease, 149 subjects with either AD or DLB have received neflamapimod for up to 24 weeks at either 40 mg BID or TID or 125 mg BID, the most commonly reported adverse events were headache (15 events, 10%), respiratory infection (11 events, 7%), diarrhea (11 events, 7%), fall, (11 events, 7%), and somnolence (seven events, 5%), all mild to moderate in severity. Headache, diarrhea, and somnolence appear to have the strongest association with neflamapimod.

There were five Serious Adverse Events reported in the 149 subjects with AD and DLB treated with neflamapimod (vs. eight who were administered placebo), involving hypokalemia, myeloma, head injury, brain tumor, and brain lesion, none of which were considered related to neflamapimod.

Adverse Events in Phase 2 Clinical Trials of Neflamapimod (CNS and non-CNS disease)

Adverse Event	Number (%) of Adverse Events Reported	
	Neflamapimod (N=217)	Placebo (N=151)
Headache	22 (10%)	7 (5%)
Diarrhea	21 (10%)	8 (5%)
Abdominal Pain	13 (6%)	8 (5%)
Respiratory infection	11 (5%)	8 (5%)
Fall	11 (5%)	7 (5%)
Dizziness	10 (5%)	4 (3%)
Back pain	10 (5%)	2 (1%)
Common cold	10 (5%)	1 (1%)

With respect to liver enzyme abnormalities, during 12 weeks of dosing at 250mg BID (i.e., four-fold higher daily dosing than in upcoming Phase 2b trial) in 44 subjects with rheumatoid arthritis, elevations in liver transaminase levels were noted in six subjects (14%). Additionally, in one subject (1%) participating in the Reverse-SD 24-week trial in mild AD, ALT and AST levels increased to three times the upper limit of normal. Subjects were asymptomatic, there were no associated increases in bilirubin, and the elevations resolved with treatment discontinuation.

In the most recently completed AscenD-LB trial involving 91 subjects with DLB, neflamapimod was well tolerated with no treatment discontinuations due to study drug-related adverse events. There were four SAEs reported in the placebo group (haematochezia, internal bleeding, intraparenchymal hemorrhage, asthma exacerbation) and two in neflamapimod BID recipients (brain lesions, head injury), all of which were considered unrelated to treatment. In addition, one SAE (brain tumor diagnosis) was reported 34 days after the last dose in a neflamapimod BID recipient. There were no SAEs or early treatment discontinuations in the neflamapimod TID recipients. Liver enzyme abnormalities were not observed in the AscenD-LB trial.

Preclinical Results

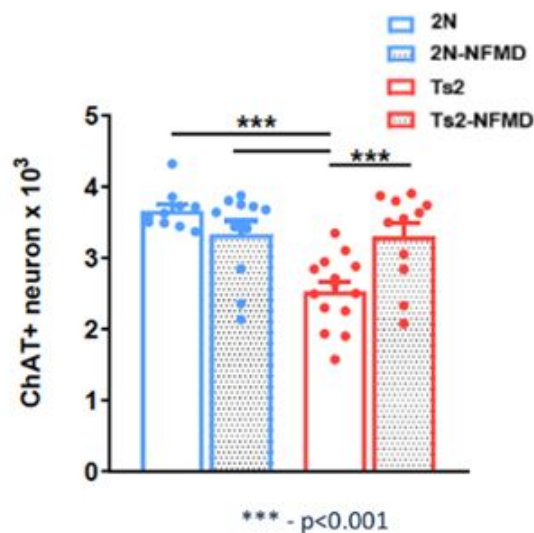
Ts2 Transgenic Mice

Nearly all individuals who have Down Syndrome, characterized by trisomic chromosome 21, develop AD by their fourth decade of life, and have typical AD pathology when autopsied at death. This may be explained by chromosome 21 containing the gene for amyloid-precursor-protein, which is the gene linked to familial or genetic early onset AD in humans. Ts2 transgenic mice is a mouse model of Down Syndrome, as it is partially trisomic at chromosome 16, which is the mouse equivalent of chromosome 21. Along with developmental behavioral abnormalities, the Ts2 mice develop typical early onset dementia pathology, including endosomal abnormalities and cholinergic neurodegeneration in the basal forebrain cholinergic system. Accordingly, Ts2 mice provide an ideal opportunity to evaluate the effects of drug treatment on basal forebrain cholinergic dysfunction and degeneration.

To evaluate the potential of neflamapimod on the neurodegenerative process, the effects of neflamapimod were evaluated in Ts2 mice. Wild-type mice, referred to as either WT or 2N, and Ts2 mice were treated over 28 days, twice daily, with either vehicle or 3 mg/kg of neflamapimod in vehicle, with nine mice in each group. Treatment was initiated at 6-7 months of age, representing a time point at which endosomal pathology and cholinergic neuronal loss is developing. To assess for effects on cholinergic neurodegeneration, neurons staining positively for choline acetyl transferase ("ChAT+" neurons), were quantitated in the region of the forebrain that is enriched for cholinergic neurons, which is known as the medial septal nucleus ("MSN").

At the end of treatment, consistent with current scientific literature, the number of cholinergic neurons in the MSN region was significantly decreased in vehicle-treated TS2 mice compared to vehicle-treated WT mice ($p < 0.001$). This effect was reversed with neflamapimod treatment, with the number cholinergic neurons in the MSN increased in neflamapimod-treated TS2 mice compared to vehicle-treated TS2 mice, and the number of ChAT+ neurons were similar to those seen in WT mice ($p < 0.001$).

Neflamapimod restores numbers of cholinergic neurons in basal forebrain (i.e., reverses disease progression) in Ts2 transgenic mouse.



Quantitated numbers of cholinergic neurons, as assessed by staining positive for ChAT+ in the MSN of the basal forebrain, in wild-type or Ts2 transgenic mice after treatment for four weeks with either vehicle or neflamapimod.

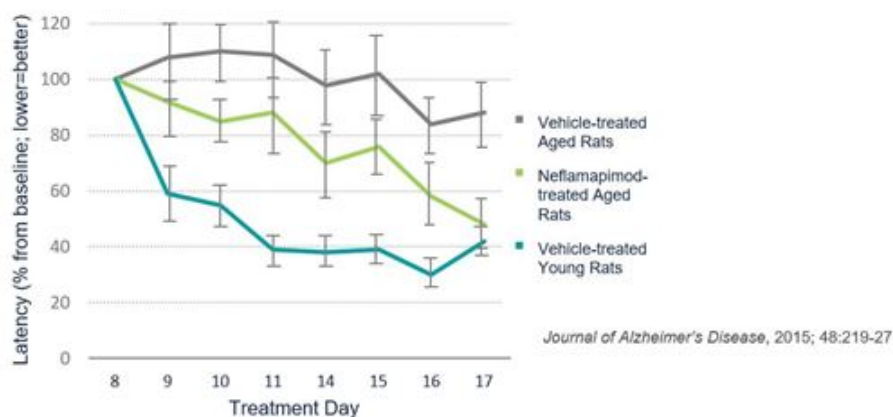
The finding of reversal of disease progression is consistent with studies in the scientific literature that suggest that “loss” of cholinergic neurons in the basal forebrain cholinergic system is not due to cell death. Rather, the “degeneration” and loss of such basal forebrain cholinergic neurons appears to be due to a loss of cholinergic phenotype and functional properties, and neuronal shrinkage, all of which in animal studies can be reversed. That is, the effect of reversing disease progression, evidenced by increased number of cholinergic neurons, is not a regenerative effect. Rather, we believe it reflects that treatment with neflamapimod is restoring the functional status of diseased neurons that don’t express ChAT, allowing them to express ChAT. There is also evidence from studies in early AD, that cholinergic phenotype loss, rather than frank neuronal death and loss, occurs in the basal forebrain of humans as well.

Aged Rat Model

To obtain preclinical proof-of-principle and confirm the role of p38 α in the development of synaptic dysfunction, we tested neflamapimod in a rat model of age-related cognitive decline. When evaluated in the Morris-Water-Maze test, rats show cognitive deficits starting at 20 to 22 months of age, which is equivalent to approximately 60 years of age in humans. Of note, because the deficits in Morris-Water-Maze performance can be fully reversed by implanting healthy cholinergic neurons in the basal forebrain, those deficits are believed to be due to basal forebrain cholinergic dysfunction and degeneration.

The published results of these tests showed that treatment with neflamapimod fully reversed the learning deficits in the Morris-Water-Maze test in 20 to 22 month old rats with identified cognitive deficits, with the performance of aged rats on the last day of testing (day 17) treated with neflamapimod at the optimal dose being significantly better than vehicle-treated aged rats ($p=0.007$ for latency; $p=0.01$ for distance) and being similar to that of young rats (i.e., fully reversed cognitive deficits). The figure below further details the results of these tests, in which two groups of 15 rats each (aged rats with cognitive deficits and a control group of young rats) received vehicle or active drug treatment for 21 days. The Morris-Water-Maze test was conducted on days 4-8 and days 11-17. The figure below shows reduction in latency (note: decreased latency indicates better performance).

Neflamapimod Improved Morris-Water-Maze Performance in Aged Rats



Neflamapimod dosing reverses cognitive deficits as assessed by Morris-Water-Maze test. At Day 17, $p=0.007$ for neflamapimod-treated aged rats compared to vehicle-treated aged rats

Planned Phase 2b Clinical Study in DLB

We expect to start during Q2 2023 a Phase 2b clinical trial of neflamapimod in subjects with DLB. The design of this study trial is based on the findings and the learnings from the Phase 2a DLB trial. The learnings from Phase 2a that we believe position the planned Phase 2b trial for success are as follows:

- The optimal dose is 40mg TID.
- Clinical endpoints that can detect effects on both cognitive and motor function (specifically, CDR-SB and TUG) perform better to distinguish drug treatment from placebo than endpoints that are purely focused on evaluating cognition. Moreover, in AD, CDR-SB is accepted by regulatory authorities as an approval endpoint. Accordingly, we have chosen CDR-SB as the primary endpoint in the Phase 2b trial.
- Subjects with pure DLB (i.e., those without AD co-pathology as evidenced by increased concentrations of plasma ptau181) appear to have a greater response to treatment. Therefore, we have chosen to exclude subjects with elevated (i.e., abnormal) levels of plasma ptau181, in the Phase 2b trial. We believe that excluding subjects with abnormal plasma ptau181 substantially increases the statistical power to demonstrate treatment effects in clinical trials of neflamapimod in DLB.

Considering the above, the planned Phase 2b clinical trial will be a randomized double-blind, placebo-controlled clinical trial of neflamapimod 40 mg administered TID in subjects with DLB. Success in the Phase 2b clinical trial will confirm and expand upon the results from Phase 2a (Study 501) ahead of any future Phase 3 trial.

Neflamapimod will be administered orally, 40 mg TID, with a second group receiving matching placebo. Each group will have at least 80 subjects (enrolling a total of 160 subjects) diagnosed with DLB by consensus criteria, including having abnormal dopamine transporter scan. Subjects with elevated plasma ptau181 (i.e., having evidence of AD co-pathology) will be excluded. Treatments (neflamapimod or placebo) will be administered for 16 weeks in the main trial (i.e., placebo-controlled portion of the study), with a 36-week open label treatment extension for subjects completing the initial 16-weeks of the trial. Following completion of informed consent procedures, subjects will enter the Screening phase of the trial. Once eligibility is confirmed and before the first dose of study drug, subjects will be randomly assigned on 1:1 basis to placebo or neflamapimod treatment. Dosing will start on Day 1 following completion of all Baseline procedures. During the placebo-controlled portion of the trial, subjects will return to the clinic at the end of weeks 2, 4, 8, 12 and 16.

The primary objective of the trial is to demonstrate that neflamapimod, compared with placebo, improves dementia severity, as assessed by change from baseline to week 16 in CDR-SB score. Secondary objectives include studying safety of neflamapimod and treatment effects on (1) cognition, assessed by a DLB-specific cognitive test battery, (2) motor function, as assessed by the TUG test, and (3) global rating of treatment effect, assessed by the ADCS-Clinician Global Impression of Change ("CGIC"). Tertiary endpoints will examine whether neflamapimod affects neuropsychiatric outcomes as assessed by the NPI-12, effect on fluctuations in cognition as assessed by the Dementia Cognitive Fluctuations Scale, impact on resting-state EEG (as well alpha-reactivity evaluated by EEG) and in a sub-set of subjects, basal forebrain atrophy assessed by structural MRI.

In January 2023, we were awarded a \$21 million grant from the NIA that is estimated to fully fund development costs associated with the planned Phase 2b trial. The NIA grant funds will be disbursed over the course of the trial as costs are incurred.

Phase 3 Development in DLB Based on Success in Phase 2b Clinical Trial

We met with the FDA in January 2020, after completion of the Reverse-SD Phase 2a trial, in an end-of-phase 2 (EOP2) meeting to discuss potential Phase 3 clinical designs that may support approval of neflamapimod for the treatment of DLB. In that meeting, the FDA stated that a single Phase 3 clinical trial of six months' treatment duration may be sufficient to support approval of neflamapimod if the trial demonstrated robust, clinically meaningful effects on cognition and on either function or a global measure (e.g., clinical global measure impression of change, CGIC). Based on those discussions, we believe that if the Phase 2b trial demonstrates significant effects on the primary endpoint CDR-SB (a clinically meaningful measure of cognition and function), the result would be highly predictive of success in Phase 3, as the Phase 3 clinical trial must replicate the Phase 2b findings over six months (vs. four months in Phase 2b). Further, the number of subjects to be enrolled in a Phase 3 trial, which at the time of the EOP2 meeting was proposed to be 250 subjects, would be adjusted based on treatment effect size observed in the Phase 2b results to provide >95% statistical power for the primary efficacy endpoint. We are also evaluating CGIC in our planned Phase 2b trial for incorporation as an endpoint in the Phase 3 clinical trial. The size of a Phase 3 clinical trial, and certain other aspects of the Phase 3 trial (e.g., choice of secondary endpoints) would be discussed with the FDA in a second EOP2 meeting that we would expect to schedule after the primary efficacy data are available from the planned Phase 2b clinical trial.

Neflamapimod in Potential Acute Indication: Recovery after Ischemic Stroke

We believe the therapeutic benefit of targeting neuroinflammation-induced synaptic dysfunction is not limited to chronic neurodegenerative diseases. A drug that improves synaptic function could also be considered for evaluation of the potential to improve brain function after acute neurological injury. In the future, we may investigate neflamapimod in the treatment of certain acute indications such as ischemia-induced stroke. To date, we have generated preclinical evidence suggesting that neflamapimod could improve recovery after ischemic stroke in an animal model.

Every year, more than 795,000 people in the United States suffer a stroke, and approximately 610,000 of these are first or new strokes. About 87% of all strokes are ischemic strokes, in which blood flow to the brain is blocked. The prognosis for recovery from stroke is influenced by a number of different factors, including stroke severity, type of stroke, location of infarct, co-morbidity with other disorders, and other clinical complications. The majority of survivors of an acute stroke demonstrate some level of neurological recovery during the three to six months after the initial event. Despite this initial period of recovery, 40 to 50% of patients exhibit persistent neurological deficits.

During the last 10 years, the medical and scientific communities have gained a better understanding of the mechanisms underlying neuronal recovery following a stroke. The major translational opportunity for therapeutics that target recovery after stroke is the time window in which intervention must be initiated. Rather than just the first few hours after the stroke (as is the case with neuroprotection, i.e., acute stroke therapy to reduce the size of stroke), the window for therapeutics that target recovery is days and even weeks after an acute stroke. Waiting to initiate therapy until 48 hours after the stroke allows inclusion of a homogenous patient population as the diagnosis and extent of the stroke can be definitively established by that time in most patients (the exception being the minority who have a "stuttering" stroke). As a result, a POC study in stroke recovery is in the range 50-100 patients per treatment arm, compared to 500+ per treatment arm in neuroprotection trials.

The scientific rationale for evaluating neflamapimod to promote recovery after stroke is that the BFC system plays a critical in recovery, particularly motor function recovery, after ischemic stroke, and that system is suppressed by residual inflammation in the weeks and months after the acute stroke event. Neflamapimod, through the same mechanisms operating in DLB, would be expected to reverse the suppression of BFC function, leading to improved recovery of motor function. Supporting that concept is our preclinical data with neflamapimod demonstrating significant improvement in neurological recovery vs. vehicle treatment, and TUG results from the AscenD-LB clinical trial where positive effects of neflamapimod on basal forebrain mediated control of movement were observed in the clinic.

In the preclinical study of neflamapimod that evaluated effects on recovery after stroke, which has been published in a peer-reviewed scientific journal, transient ischemia of sufficient duration was induced such that significant neurologic disability developed without mortality, and the neurologic disability did not substantially reverse during follow-up without therapy. These rats were then treated with either vehicle or one of two different doses of neflamapimod. The three groups in the study were: vehicle control (n = 18), 1.5 mg/kg neflamapimod (n = 21) and 4.5 mg/kg neflamapimod (n = 21). Six weeks of neflamapimod treatment, starting at 48-hours after stroke, led to substantial improvement on multiple parameters of neurologic function compared to vehicle controls ($p < 0.001$ for each of global neurologic scores; motor and sensory specific tests).

We have no immediate plans to initiate a clinical trial evaluating neflamapimod for treatment of acute stroke. However, we have had extensive discussions with stroke experts and have designed a POC trial to improve recovery after ischemic stroke. The potential clinical trial would be a 12-week placebo-controlled phase 2 POC trial that would enroll 120 subjects with uncomplicated acute moderate or moderate-to-severe ischemic stroke in the anterior circulation stroke (confirmed by MRI) and demonstrated motor deficits (hemiparesis or hemiplegia). Subjects would be randomized 1:1 to placebo or neflamapimod 40 mg TID for 12 weeks, starting three to seven days after the acute stroke. The primary endpoint would be motor function by the Fugl-Meyer motor scale at the end of three months treatment. Secondary endpoints would include the Time Up and Go test, Montreal Cognitive Assessment, and the proportion of subjects with modified Rankin Scale score ≤ 2 (no to slight disability).

Neflamapimod in Early Onset Alzheimer's Disease

EOAD is defined as AD dementia with onset of the dementia prior to age 65. It is the most common form of early-onset AD, representing between one-third and one-half of individuals with dementia onset before age 65. The Alzheimer's Association estimates the number of individuals in the United States with EOAD in 2023 to be approximately 200,000.

While the age cut-off is arbitrary, a variety of observations indicate that EOAD is a distinct biological and clinical entity from LOAD, with substantial differences in clinical presentations, greater genetic predisposition for EOAD, differences in neuropathologic burden and topography, and differences in functional connectivity. For example, in EOAD patients, memory problems appear less frequently, but loss of visuo-spatial functioning, language, attention, and executive function are more prevalent. In addition, functional MRI and other studies indicate that, compared with LOAD, EOAD impacts fronto-parietal networks, with a relative sparing of the posterior default mode network and medial temporal lobe, i.e., the hippocampus. As well, the severity of neuropsychiatric symptoms (anxiety, night-time behaviors and motor disturbances) is higher in EOAD than in LOAD.

That EOAD and LOAD are distinct clinical entities was further demonstrated in a recently published cross-sectional study in a large cohort (n=1750) of subjects with autopsy-confirmed sporadic (i.e., non-familial) AD. Within the cohort, there was a clear binomial distribution for age of onset (i.e., two distinct patient populations), an early-onset population with a mean onset at age 57.2 (± 3.8) years and a late-onset population with a mean age of onset of 76.7 (± 7.5) years. As the point of intersection between the two distributions (the age at onset, which is equally likely to belong to both) was age 63.0 years, this age cutoff was utilized to categorize the subjects in the cohort as having EOAD or LOAD. By this definition, the subjects with EOAD in their cohort were more likely than those with LOAD to present with noncognitive behavioral or motor symptoms or nonmemory cognitive complaints, and had more executive dysfunction, but less language impairment, on objective cognitive testing. Subjects with EOAD also had faster cognitive and functional decline than those with LOAD. Moreover, at autopsy, subjects with EOAD were more likely than those with LOAD to have pure AD pathology, without concomitant non-AD pathology, while subjects with LOAD were more likely than those with EOAD to have cerebrovascular pathology, MTL/hippocampal sclerosis, and in a sub-analysis, hippocampal TDP-43.

While survival from diagnosis is similar between EOAD and LOAD, with an age of onset 20 years lower, the impact in terms of life-years lost for each individual impacted is significantly greater with EOAD compared to LOAD.

While the relative contribution of pathogenic mechanisms in the cholinergic system as compared to those in the hippocampus remains controversial for LOAD, the literature of the last five years indicates that the earliest, and primary pathology in EOAD is in the basal forebrain cholinergic system and the dysfunction and degeneration of these neurons drives neurodegeneration in other regions of the brain. As such, we believe, given our drug's specific activity against cholinergic degeneration, within the AD spectrum neflamapimod has the greatest potential as a single agent in EOAD.

We have no near-term plans to initiate a clinical trial evaluating neflamapimod for treatment of EOAD. Rather, if we are able to demonstrate, as we expect, proof-of-concept in DLB with data from the planned Phase 2b clinical trial, we would pursue clinical development in EOAD. Because disease progression in early-stage disease is more consistent in EOAD compared to LOAD, we would expect a registrational clinical trial that was designed to show effects on disease progression would be substantially smaller than that required for LOAD (300-400 subjects vs. 800-1000 subjects) and of 12 months duration (vs. 18 months for LOAD).

Neflamapimod in LOAD

The defining clinical characteristics of LOAD are deficits in episodic memory (the recollection of everyday events) and the driving pathology is in the hippocampus, the part of the brain in which episodic memory is formed. Accordingly, the amyloid beta therapies have been developed as a treatment for LOAD based on preclinical data demonstrating that amyloid beta has deleterious effects on synaptic function in the hippocampus. However, scientific literature also indicates that degeneration of the basal forebrain cholinergic system also contributes to disease expression and progression in LOAD, and we believe that a reason for the limited success of amyloid beta directed therapies is that they do not impact disease progression in the basal forebrain. Moreover, in preclinical studies, p38 α expression increased amyloid beta production, while reducing p38 α activity decreased amyloid pathology; and neflamapimod treatment of transgenic AD mice reduced amyloid beta levels and in the Ts2 mice reduced the expression of the major enzyme (beta secretase) that produces amyloid beta. Based on this science, we believe there is a strong rationale for combining neflamapimod with amyloid beta directed therapies. However, given the costs associated with developing therapies for LOAD (costs that are further increased when developing combinations) we would expect only to conduct such combination trials in the context of a collaboration with a larger pharmaceutical company, ideally one that has either late-stage development or an approved amyloid beta directed therapy in its portfolio. However, we are not yet a party to any such agreement and have not yet identified any potential collaborators. Accordingly, at this time, we have not included LOAD in our pipeline chart.

EIP200 (Novel Co-Crystal of Neflamapimod)

We have an issued patent, set to expire in 2038, in the United States for novel co-crystals of neflamapimod with identified, specific, Generally Recognized as Safe compounds that have the potential to improve the solubility and other physical properties of neflamapimod. The development of one of these co-crystals as a product would be supported by composition of matter protection afforded by this patent, providing additional patent protection if we developed a such co-crystal product ourselves and/or the opportunity to license such a product to another pharmaceutical company while retaining the rights to neflamapimod. The ability to develop one or more of these co-crystal products requires a fuller evaluation of the potential manufacturing processes than has been performed to date.

Neflamapimod – History of Development

History

Neflamapimod was originally discovered at Vertex, which initiated clinical investigations in 1999 to determine the effects of the drug on rheumatoid arthritis. During its clinical investigations of neflamapimod, Vertex completed single and multi-dose Phase 1 studies and initiated Phase 2a development in rheumatoid arthritis. A total of approximately 150 healthy volunteers and patients received neflamapimod in Vertex-sponsored studies for up to one month at 750 mg twice daily and up to 3 months at a dose of 250 mg twice daily.

In a Phase 2a trial in active rheumatoid arthritis conducted by Vertex, a total of 59 healthy volunteers and patients (44 on active drug of 250 mg, and 15 on placebo, twice daily) were enrolled in a 12-week treatment. In this trial, a statistically significant effect of neflamapimod administration on American College of Rheumatology 20 (“ACR20”) response rate was demonstrated ($p = 0.027$ in the primary endpoint analysis: area-under-the-curve of ACR20 response over the 12-week trial period). In a pharmacokinetic/pharmacodynamic analysis, neflamapimod administration also reduced C-reactive protein and IL-6 levels with increasing cumulative drug exposure.

Neflamapimod was generally well tolerated in this rheumatoid arthritis (“RA”) Phase 2a trial. The most common adverse events associated with neflamapimod were abdominal pain (21% of the 44 healthy volunteers), diarrhea (18%), infection (16%), headache (14%), increased aspartate aminotransferase (14%) and increased alanine aminotransferase (11%). No treatment-emergent neurologic events were seen. Regarding liver function test abnormalities, transaminase levels returned to normal after treatment discontinuation and were not associated with bilirubin elevations. Liver enzyme elevations are a well-known dose-dependent clinical side effect of p38 MAPK inhibitors. In the case of neflamapimod however, we believe the threshold for inducing liver enzyme elevation is a dose level of 250 mg twice daily when administered for more than 4 weeks, which on a daily dose level is four-fold higher than the 40mg TID dose regimen we are moving forward in DLB and other CNS indications (500 mg per day in RA vs. 120 mg per day in DLB and other CNS indications).

Toxicology

A full chronic repeated dose toxicology program has been completed in rodents (rats) and non-rodents (dogs). In the rodent species, in the six-month toxicology study, no human relevant findings were evident at dose levels that provided plasma neflamapimod drug concentration levels approximately ten-fold higher than those achieved in the AD clinical trials. In shorter-term studies, the primary target organ was the liver, with findings commencing at plasma drug concentration levels 20-fold higher than the AD clinical trial exposures. In the non-rodent species, in 9- and 12-month toxicology studies, dose dependent findings were evident beginning at plasma neflamapimod drug concentrations more than ten-fold higher than achieved with 40 mg twice daily in AD clinical trials, with minimal to equivocal findings at that dose level in the liver, bone marrow and CNS. The CNS findings demonstrated damage to axons, or nerve fibers, primarily in the spinal cord. p38 α and p38 β have been reported to have a role in transport of proteins in axons, and therefore we believe these toxicity findings are related to the inhibition of both p38 α and p38 β at the very high doses administered in the non-rodent studies. The doses we are using in our clinical trials are at least ten-fold lower than the doses at which these effects were observed.

Acquisition by EIP

Vertex ultimately discontinued its pursuit of neflamapimod in the early 2000s to focus on the clinical development of a therapy for rheumatoid arthritis with a different p38 α inhibitor, which, unlike neflamapimod, does not enter the brain. Neflamapimod lay dormant with Vertex until we expressed our interest in exploring the drug for other indications. Based on our team’s previous direct experience with this compound and our understanding of its profile and emerging science around p38 α in the brain, we entered into an Option and License Agreement with Vertex in August 2012, and subsequently acquired an exclusive license from Vertex in 2014 to develop and commercialize neflamapimod for the treatment of AD and other neurodegenerative diseases.

Neflamapimod – Regulatory Status

We submitted an IND application to the DNP of the FDA in February 2015. The DNP cleared our application in March 2015, and the IND remains open and active.

The FDA granted neflamapimod Fast Track designation for the treatment of DLB in October 2019.

Following a review of the long-term animal toxicology studies discussed above, the DNP placed a partial clinical hold on our first Phase 2a in mild AD (Study 303) in August 2015, limiting administration of neflamapimod to doses that lead to plasma drug levels which provide at least a 10-fold safety margin to the plasma drug levels in animals that in long-term animal toxicity studies had previously led to minimal or equivocal findings in the liver, bone marrow and CNS. At the present time, this partial clinical hold effectively limits our clinical dosing in the United States to 40 mg of neflamapimod three times daily in patients with a weight of greater than or equal to 60 kg (132 pounds), based on agreements with the FDA and on our current understanding of plasma drug levels achieved with neflamapimod in humans. As our current plans across our indications do not envision surpassing this dose level, we do not expect this partial clinical hold to impact our ongoing and planned clinical trials.

In Europe, clinical trial applications in support of our clinical trials have been reviewed and approved by the national regulatory authorities in each of the Netherlands, United Kingdom, Czech Republic and Denmark. In addition, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (the French national regulatory authority) has reviewed and approved a clinical trial application for an investigator-initiated study of neflamapimod in Toulouse, France.

Vertex Agreement

In August 2012, we entered into an Option and License Agreement with Vertex Pharmaceuticals Incorporated, including all subsequent amendments (the “Vertex Agreement”). The Vertex Agreement granted us an option to acquire an exclusive worldwide license to develop and commercialize neflamapimod for the diagnosis, treatment and prevention of AD and other neurodegenerative diseases. In August 2014, we exercised an option to acquire the license to neflamapimod.

The Vertex Agreement contains certain milestone events and the related payments that we would be obligated to make to Vertex if and when such events occur. Each milestone payment is payable only once for each distinct licensed product, upon the first occurrence of the applicable milestone event. The first expected milestone events concern filing of an NDA, with the FDA for marketing approval of neflamapimod, in the U.S., or a similar filing for a non-U.S. major market, as specified in the Vertex Agreement. The Vertex Agreement provides that we will make royalty payments to Vertex in the event aggregate net sales, as defined in the agreement, for a commercialized licensed product meet specified thresholds. Such royalties will be on a sliding scale of percentages of net sales in the low- to mid-teens, depending on the amount of net sales in the applicable years. We are also obligated to make a milestone payment to Vertex upon net sales reaching a certain specified amount in any 12-month period. The Vertex Agreement states that royalties will be reduced by 50% during any portion of the royalty term when there is no valid claim of an issued patent within specified patent rights covering the licensed product. We also have the right to deduct, on a country by country basis, from royalties otherwise payable to Vertex under the terms of the Vertex Agreement, 50% of all royalties, upfront fees, milestones and other payments paid by us or any of our affiliates or sublicensees to third parties under licenses that are necessary for the development, manufacture, sale or use of a licensed product, provided that in no event will the royalty payable to Vertex be reduced to less than 50% of the rates specified in the Vertex Agreement, subject to certain adjustments specified therein.

The Vertex Agreement provides that we may sublicense the rights granted to us by Vertex, in whole or in part, to a third party (through multiple levels of sublicensing) (i) who is providing services to us in connection with the manufacture or development of the licensed product, solely for the purpose of providing such services, or (ii) with the prior written consent of Vertex, which shall not be unreasonably withheld.

The license term under the Vertex Agreement is deemed to have commenced on August 21, 2014, and continues until the expiration of the royalty term, unless sooner terminated in accordance with the terms of the Vertex Agreement. The royalty term commences on the first commercial sale of a licensed product and ends upon the later of (i) the date of expiration, unenforceability or invalidation of the last valid claim of certain specified underlying patent rights, or (ii) ten years after the date of such first commercial sale. Upon the expiration of the royalty term, the license will convert to a perpetual, fully paid-up non-royalty bearing license with the same scope.

The Vertex Agreement may be terminated by us for any reason upon 90 days’ prior written notice to Vertex if such termination occurs before receipt of the first marketing approval of a licensed product, and otherwise upon twelve months’ prior written notice to Vertex. Either party may terminate the Vertex Agreement if the other party is in material breach of its obligations thereunder, following a 60-day notice and cure period, or if the other party files for bankruptcy, reorganization, liquidation, receivership, or an assignment of a substantial portion of assets to creditors. The Vertex Agreement also provides that in the event we materially breach any of certain specified diligence obligations as to a specific major market, Vertex’s sole remedy for such breach, following the applicable notice and cure period, will be to terminate the license as to such specific major market country.

Sales and Marketing

We do not currently have any infrastructure for the sales, marketing or distribution of an approved drug product. In order to market and successfully commercialize neflamapimod or any other future product candidate, to the extent it or they are approved, we must either develop these capabilities internally or make arrangements with third parties to perform these services. We may also collaborate with strategic partners that have experience in these fields. There are significant expenses and risks involved in establishing our own sales, marketing and distribution functions, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Alternatively, to the extent that we depend on third parties for such services, any revenues we receive will depend upon the efforts of those third parties, and there can be no assurance that such efforts will be successful.

Manufacturing

We do not own or operate manufacturing facilities, nor do we have plans to develop our own manufacturing operations in the foreseeable future. Our lead product candidate, neflamapimod, is a small molecule drug that is manufactured using commercially available technologies.

The planned Phase 2b clinical trial will be conducted with drug substance (also known as “Active Pharmaceutical Ingredient” or “API”) has already been manufactured. In addition, we have sufficient drug substance available to cover the anticipated needs for Phase 3 in DLB. This drug substance was manufactured at an established commercial contract manufacturing organization, that is approved for and manufactures drug both for investigational use and marketed products. We would anticipate utilizing the company for clinical trials beyond the Phase 3 clinical trial in DLB, as well potentially for commercial use. However, supplies of our neflamapimod drug substance could be interrupted from time to time, and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of drug substance could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates.

We also currently rely on a third-party contract manufacturing organization (different than that for drug substance) for the manufacture of our neflamapimod drug product. We have used the same manufacturer for our neflamapimod drug product in all our clinical trials to date. If neflamapimod is ultimately approved for commercial sale, we expect to continue to rely on third-party contractors for manufacturing the drug product. Although we intend to do so prior to any commercial launch, we have not yet entered into long-term agreements for the commercial supply of either drug substance or drug product with our current manufacturing providers, or with any alternate manufacturers.

Competition

Given the potential market opportunity for the treatment of DLB and other neurodegenerative diseases, an increasing number of established pharmaceutical firms and smaller biotechnology/biopharmaceutical companies are pursuing a range of potential therapies for these diseases in various stages of clinical development.

While there are numerous companies pursuing AD disease modifying approaches, there are a limited number of companies and disease modifying approaches for DLB.

With regard to public biopharmaceutical companies that we would consider competitive with our approach, and actively evaluating treatments in DLB, we are aware of Eisai Co. Ltd., or Eisai, Cognition Therapeutics, Inc. and Athira Pharma, Inc. All three companies are in Phase 2 clinical trials, and none have reported positive (statistically significant improvement over placebo) clinical trial results in DLB at this time.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize, including neflamapimod, may compete with existing therapies and new therapies that may become available in the future.

Our competitors may have significantly greater financial resources, an established presence in the market, and significantly greater expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of neflamapimod, and any other product candidates that we develop to address DLB and other CNS diseases, if approved, are likely to be their efficacy, safety, convenience, price, the level of competition, and the availability of reimbursement from government and other third-party payors. Our potential commercial opportunity could also be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and our product candidates that are important to the development and implementation of our business.

We have made a number of discoveries related to our lead product candidate, neflamapimod, which are reflected in ten main patent families, each of which we wholly own (dates below are without consideration of potential patent term extension, see section titled “— *U.S. Patent-term Extension*” below):

- The first patent family relates to methods of treating patients suffering from AD, as well as methods of reducing amyloid plaque burden. In this family, we hold issued patents in the United States, Europe, Japan, China, Canada, Australia, and Hong Kong. These patents are set to expire in 2032.
- The second patent family relates to the use of neflamapimod for improving cognition. In this family, we hold issued patents in the United States, Europe, Japan, and a pending application in China. These patents are set to expire in 2035.
- The third patent family relates to co-crystals of neflamapimod in this family, we hold an issued patent in the United States. This patent is set to expire in 2038.
- The fourth patent family relates to methods for promoting recovery of function in patients who have suffered acute neurologic injuries, including those resulting from various forms of stroke. In this family, we hold an issued patent in the United States, Europe, and Japan, and pending applications in Korea and Hong Kong. These patents are set to expire in 2035-2036.
- The fifth patent family relates to methods of treating patients suffering from dementia. In this family, we have an issued patent the United States for the treatment to patients with MCI to improve episodic memory and a pending application in Europe. Patents that issue in this family, if any, are expected to expire in 2037.

- The sixth patent family relates to formulations of neflamapimod, including pharmaceutical compositions for oral administration exhibiting desirable pharmacokinetics and processes for the manufacture thereof. In this family, we have an issued patent in the United States that is set to expire in 2039.
- The seventh patent family relates to the treatment of DLB. In this family we have pending applications in the United States, Europe, Japan, China, Canada, and Hong Kong. Patents that issue in this family, if any, are expected to expire in 2040.
- The eighth patent family is co-owned by Boston University and relates to methods of treating prion disease. In this family, we have a pending application in the United States. Patents that issue in this family, if any, are expected to expire in 2040.
- The ninth patent family relates to treatment of gait dysfunction related to neurodegenerative disease. An International Application is pending. Patents that issue in this family, if any, are expected to expire in 2041.
- The tenth patent family relates to treatment of a subpopulation of patients having DLB but no substantial Alzheimer's like tau pathology. Patents that issue in this family, if any, are expected to expire in 2042.

Pursuant to the terms and conditions of the Vertex Agreement, Vertex has granted us an exclusive license under specified Vertex patent rights, including U.S. patent No. 5,945,418, which relates to the composition of matter for neflamapimod. This patent expired in 2017.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the USPTO delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We also rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements and invention assignment agreements with our collaborators, employees and consultants, as we determine necessary. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses from third parties or cease certain activities.

From time to time, we may find it necessary or prudent to obtain licenses from third party patent owners. Where licenses are available at reasonable cost, such licenses are considered a normal cost of doing business. In other instances, we may use the results of freedom-to-operate studies to guide our early-stage research away from areas where we are likely to encounter obstacles in the form of third-party intellectual property. We strive to identify potential third-party intellectual property issues in the early stages of research in our programs in order to minimize the cost and disruption of resolving such issues.

Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us.

For more information, please see “*Risk Factors—Risks Related to Our Intellectual Property.*”

Government Regulation

The FDA and comparable regulatory authorities in other countries impose requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These requirements can, in some instances, be substantial and burdensome. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of pharmaceutical products. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development and approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve a pending NDA, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters or other notices of violation, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business and results of operations.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of nonclinical laboratory tests, potentially animal studies and formulation studies in compliance with the FDA’s GLP regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an IRB covering each clinical trial site before each trial may be initiated at that site;
- Performance of adequate and well-controlled human clinical trials in accordance with GCP and other clinical trial-related requirements to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA seeking marketing approval;
- A determination by the FDA within 60 days of its receipt of an NDA that the NDA is sufficiently complete to permit a substantial review, in which case the NDA is filed;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity;
- Satisfactory completion of FDA audits of clinical trial sites that generated data in support of the NDA to assure compliance with GCPs and the integrity of the clinical data and/or FDA audits of the nonclinical studies submitted as part of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of an FDA advisory committee, if one was involved, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and IND

Nonclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for the investigational product's therapeutic use. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA to specify that nonclinical testing for drugs may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations.

An IND sponsor must submit the results of preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans, and it must become effective before human clinical trials may begin. Some long-term nonclinical testing may continue even after the IND is submitted and clinical trials have been initiated. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators (generally physicians not employed by or under the trial sponsor's control) in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB acting on behalf of each institution participating in the clinical trial must review and approve the plan for any clinical trial before it is initiated at that institution. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials also must be submitted within specific timeframes to the National Institutes of Health ("NIH"), for public dissemination on the clinicaltrials.gov data registry. Information related to the investigational product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. The NIH's Final Rule on [ClinicalTrials.gov](https://clinicaltrials.gov) registration and reporting requirements became effective in 2017, and the government has recently begun enforcing those requirements against non-compliant clinical trial sponsors.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into a small number of healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to evaluate the efficacy and safety of the product for its intended use, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product as well as an adequate basis for marketing approval.
- Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the investigational drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. It is possible that Phase 1, Phase 2 or Phase 3 trials may not be completed successfully within any specified period, or at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Concurrent with clinical trials, companies may perform additional nonclinical studies and develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that a drug candidate does not undergo unacceptable deterioration over its proposed labeled shelf life.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the nonclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA.

Under the Prescription Drug User Fee Act (“PDUFA”), the submission of an NDA is subject to a substantial application user fee, unless an exemption or waiver applies, and the sponsor of an approved NDA is also subject to an annual program fee. FDA typically adjusts these PDUFA user fees on an annual basis. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may refuse to file the application and request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt and inform the sponsor by the 74th day after the FDA’s receipt of the submission whether an application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product’s continued safety, quality and purity. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its review of a new molecular-entity (“NME”) NDA and respond to the applicant, and six months from the filing date of an NME NDA designated for priority review. For non-NME NDAs, the review goals are ten months from the date of receipt for a standard application and six months from the date of receipt for a priority submission. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information.

The FDA also may require development of a REMS plan if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve an NDA without a REMS, if one is required.

Further, the FDA may refer an application for a novel drug, or a drug that presents difficult questions of safety or efficacy, to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making final agency decisions on marketing approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A complete response letter generally describes all of the specific deficiencies in the NDA and contains a statement of specific conditions that must be met in order to secure final approval of the NDA. A complete response letter may require substantial additional clinical or nonclinical testing or other information in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the legal or regulatory criteria for approval. If a complete response letter is issued, the applicant may choose either to resubmit the NDA, addressing all of the deficiencies identified in the letter, or to withdraw the application. If and when all deficiencies have been addressed to the FDA’s satisfaction in a resubmitted NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued complete response letter in either two or six months, depending on the type of information included.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, priority review, and breakthrough therapy designation, which are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients as quickly as possible.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a Fast Track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, Fast Track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting.

The FDA may grant priority review designation to drugs for serious conditions that offer major advances in treatment or provide a treatment where no adequate therapy exists. When a marketing application is submitted with a request for priority review, the FDA determines on a case-by-case basis whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an NME NDA from the date of filing (or from ten months to six months from the date of receipt for a non-NME NDA). Most products that are eligible for Fast Track designation are also likely to be considered appropriate to receive priority review of their marketing applications.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast Track designation, priority review, and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. We may explore some of these opportunities for our product candidates as appropriate.

Separately from these three available designation programs, products tested for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval. Such products may be approved by the FDA on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than IMM that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug may be subject to expedited withdrawal procedures. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

As part of the Consolidated Appropriations Act for 2023, Congress provided the FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on FDA's website. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows the FDA to withdraw approval of the drug. Congress also recently amended the law to give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. All promotional materials for products approved for marketing under the accelerated approval program are subject to prior review by the FDA.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, or making changes to manufacturing processes or facilities, are subject to prior FDA review and approval. Such modifications to the drug may require the applicant to develop additional data or conduct additional nonclinical studies or clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

As previously noted, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, or on the manufacturer or holder of an approved NDA, including recall or product seizure.

Once an approval of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or other enforcement-related letters, or holds on post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- Product seizure or detention, or refusal to permit the import or export of products; and
- Injunctions or the imposition of civil or criminal penalties;
- Consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and/or
- Mandated modification of promotional materials and labeling and the issuance of corrective information.
- The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although physicians may prescribe legally available drugs for unapproved uses or patient populations (known as “off-label use”), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Prescription drug promotional materials also must be submitted to the FDA in conjunction with their first use.

U.S. Patent-term Extension

Depending upon the timing, duration and specifics of FDA approval of a drug candidate, certain U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments permit extension of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent-term extension period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Regulatory Exclusivity for Small-Molecule Drug Products

With passage of the Hatch-Waxman Amendments, Congress enacted Section 505(b)(2) of the FDCA and also authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an ANDA to the agency. In support of such applications, a generic manufacturer may rely on the nonclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug (“RLD”). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.”

Following approval of an ANDA, the FDA indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

To the extent that a Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, such an applicant also is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Congress recently directed FDA to perform therapeutic equivalence evaluations for certain 505(b)(2) drugs no later than 6 months after approval when the applicant requests such an evaluation.

Specifically, an ANDA or 505(b)(2) applicant for a follow-on drug product must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product’s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA or a 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA or a 505(b)(2) NDA in question has been accepted for filing by the FDA. The NDA owner and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or a 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the follow-on applicant.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the reference product has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

U.S. Coverage and Reimbursement

Significant uncertainty exists in the U.S. as to the coverage and reimbursement status of any new product which has been approved. Drug sales in the U.S. depend in part on the availability of adequate financial coverage and reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Drug prices can be subject to challenge, reduction or denial by payors.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Sales of drug products depend substantially on the extent to which the costs of those products will be paid by third-party payors.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Third-party payors may not consider certain drugs to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on a drug developer's investment in drug development.

In August 2022, President Biden signed into the law the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. Starting in 2023, a manufacturer of drugs covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities but their impact on the biopharmaceutical industry in the United States remains uncertain. In addition to the IRA's drug price negotiation provisions, President Biden's Executive Order 14087, issued in October 2022, called for the CMS innovation center to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that may lead to appears to be leading to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us.

Other U.S. Healthcare Laws, Regulations, and Compliance Requirements

We are subject to various federal and state healthcare laws. These laws may impact, among other things, our proposed sales and marketing programs for future FDA-approved drug products. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our operations include, but as not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value;
- federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent;
- provisions of HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by HITECH and its implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- the federal Physician Payment Sunshine Act, which require manufacturers of certain drugs, medical devices, and biologics to track and report to CMS payments and other transfers of value they make to U.S. physicians, certain advanced non-physician health care practitioners, and teaching hospitals as well as physician ownership and investment interests in the manufacturer.

Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Prescription drug products also must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Regulation Outside the United States

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

To market our future products in the European Economic Area (“EEA”) (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization (“MA”). There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, is based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, including neurodegenerative disorders. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the procedures described above, before granting the MA the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the nonclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Scientific Advisory Board

We have assembled a highly qualified scientific advisory board comprised of thought leaders in the fields of cell biology, intracellular signal transduction, neurotherapeutics, and translational neuroscience.

Name	Affiliated Entity
Ole Isacson, Dr.Med.Sci.	Professor of Neurology at Harvard Medical School, Founding Director of the Neuroregeneration Research Institute at McLean Hospital
Lewis Cantley, Ph.D.	Professor of Cell Biology at Harvard Medical School. Prior to this appointment, he was the Margaret and Herman Sokol Professor and Meyer Director of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medical College/Ronald P. Stanton Clinical Cancer Program at New York Presbyterian Hospital (2012-22)
Jeffrey Cummings, M.D., Sc.D.	Joy Chambers-Grundy Professor of Brain Science and the Director of the Chambers-Grundy Center for Transformative Neuroscience at the UNLV School of Integrated Health Sciences. Prior to UNLV, Dr. Cummings served as founding director of the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, and as director of the Mary S. Easton Center for Alzheimer's Disease Research, and director of the Deane F. Johnson Center for Neurotherapeutics, both at UCLA.
Heidi McBride, Ph.D.	Canada Research Chair in Mitochondrial Cell Biology, Professor in the Department of Neurology and Neurosurgery at McGill University

Corporate Information

We were originally formed in 2010 as a limited liability company in Massachusetts under the name EIP Pharma, LLC. On March 28, 2018, we completed a reorganization whereby we converted from a Massachusetts limited liability company to a corporation incorporated under the laws of the State of Delaware under the name EIP Pharma, Inc. Our principal executive offices are located at 20 Park Plaza, Suite 424, Boston, Massachusetts 02116, and our telephone number is (617) 744-4400.

Employees

As of April 1, 2023, we had four employees, of whom all were full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be good. We also engage outside consultants and contractors with unique expertise and skills for specific purposes.

Our success depends upon our ability to attract and retain highly qualified management and technical employees. Talent management is critical to our ability to execute our long-term growth strategy, including providing career growth, on-the-job learning opportunities and competitive compensation. We are committed to an inclusive culture which values equality, opportunity and respect. We are focused on the engagement and empowerment of our employees through the demonstration of our foundational values.

Workforce Compensation and Pay Equity

We provide robust compensation and benefits programs to help meet the needs of our employees. We provide our full-time employees with highly competitive salaries, as well as a bonus and/or commission plan, a matching 401(k) Plan, healthcare and insurance benefits, paid time off and family leave. We also provide our employees with targeted equity-based grants with vesting conditions designed to facilitate retention through the opportunity to benefit financially from our growth and profitability.

Company Culture

We expect all of our employees and contractors to observe the highest levels of business ethics, integrity, mutual respect, tolerance and inclusivity. An “open door” policy is maintained at all levels of the organization and any form of retaliation against an employee reporting or registering complaints in the event of any violation of our policies is strictly prohibited.

Employee Engagement and Wellness

The success of our business is fundamentally connected to the physical and mental well-being of our people. Accordingly, we are committed to the health, safety and wellness of our employees and contractors. We provide our employees with a wide range of benefits, including benefits directed at their health, safety and long-term financial security.

Legal Proceedings

As of April 1, 2023, we were not a party to any material legal proceedings.

DIFFUSION MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements of Diffusion and accompanying notes appearing elsewhere in this proxy statement/prospectus/information statement. Some of the information contained in this discussion and analysis or set forth elsewhere in this proxy statement/prospectus/information statement, including information with respect to Diffusion's plans and strategy for its business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set out under the section titled "Risk Factors" of this proxy statement/prospectus/information statement, Diffusion's actual results could differ materially from the results described in or implied by these forward-looking statements. See also the section titled "Cautionary Statement Concerning Forward-Looking Statements" of this proxy statement/prospectus/information statement.

Overview

Diffusion is a biopharmaceutical company that has historically focused on developing novel therapies that may enhance the body's ability to deliver oxygen to the areas where it is needed most. Diffusion's most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including hypoxic solid tumors like GBM.

In early 2022, Diffusion identified the pursuit of an opportunistic transaction with the potential to complement and diversify its portfolio of product candidates as one of its key strategic objectives intended to enhance long-term value for its stockholders. In pursuit of this objective, in July 2022, Diffusion engaged CG as its financial advisor to support Diffusion's process and, in October 2022, following further deterioration of the public capital markets throughout 2022 and the corresponding increase in the cost of capital for small biopharmaceutical companies, Diffusion publicly announced its board of directors' authorization of an expanded evaluation and review of potential strategic transactions, including a joint venture, licensing, merger, reverse merger, sale or divestiture of some of proprietary technologies or a sale of Diffusion, among others.

On March 30, 2023, Diffusion, Merger Sub and EIP entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into EIP, with EIP surviving the merger as the wholly-owned subsidiary of the combined company. If consummated, immediately following the effective time of the Merger, former EIP stockholders are expected to own approximately 77.26% of the outstanding shares of our common stock, and stockholders of Diffusion as of immediately prior to the effective time of the Merger are expected to own approximately 22.74% of the outstanding shares of common stock, in each case, assuming Parent Net Cash (as defined in the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million. The actual amount of Parent Net Cash expected to be delivered at Closing will depend on many factors, including among others, the date of the closing, and no assurance can be given as to the actual amount of Parent Net Cash that will be delivered.

If the Merger is completed, the combined company will focus on developing EIP's product candidates. If the Merger is not completed, we will reconsider our strategic alternatives and may pursue one of the following courses of action, which we currently believe are the most likely alternatives if the Merger is not completed:

- *Pursue another strategic transaction similar to the Merger.* We may resume our process of evaluating other companies interested in pursuing a strategic transaction with us and, if a candidate is identified, focus our attention on negotiating and completing such a transaction with such candidate.
- *Dissolve and liquidate its assets.* If we are unable, or do not believe that we will be able, to find a suitable candidate for another strategic transaction in the best interests of our stockholders, we may dissolve and liquidate its assets. In the event of dissolution, we would be required to pay all its debts and contractual obligations and to set aside certain reserves for potential future claims. If we dissolve and liquidate our assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to our stockholders after paying our debts and other obligations and setting aside funds for its reserves.

Financial Summary

As of December 31, 2022, Diffusion had cash, cash equivalents, and marketable securities of \$22.5 million. Diffusion has incurred operating losses since inception, has not generated any product sales revenue, and has not achieved profitable operations. Diffusion has incurred net losses of \$15.6 million and \$24.1 million for the years ended December 31, 2022 and 2021, respectively. To date, Diffusion has funded its operations and short-term liquidity needs primarily through the issuance and sale of Diffusion Common Stock, warrants to purchase Diffusion Common Stock, convertible debt, and convertible preferred stock. Diffusion expects to continue funding its operations through similar means for the foreseeable future, assuming the availability of additional capital, though Diffusion may enter into strategic partnerships or other alternative transactions in order to fund its ongoing capital requirements.

- Diffusion's accumulated deficit as of December 31, 2022, was \$145.6 million and it expects to continue to incur substantial losses in future periods for the foreseeable future, including any costs related to:
 - its ongoing strategic review process;
 - any additional studies Diffusion may undertake to evaluate its current or future product candidates, including other preclinical and clinical studies to support the filing of any NDA with the FDA;
 - other research, development, and manufacturing activities designed to develop and optimize formulation, manufacturing processes, dosage, dose forms, and other characteristics prior to regulatory approval;
 - the maintenance, expansion, and protection of its global intellectual property portfolio;
 - the hiring of additional clinical, manufacturing, scientific, sales, or other personnel;
 - research and development related to any other product candidates Diffusion may acquire or in-license in the future; and
 - investments in operational, financial, and management information systems.

Subject to the outcome and timing of Diffusion's ongoing strategic review process, Diffusion currently expects that its existing cash, cash equivalents and marketable securities as of December 31, 2022 are sufficient to fund its current operations for at least 12 months following the issuance of these financial statements.

Financial Operations Overview

Revenues

Diffusion has not yet generated any revenue from product sales. Diffusion does not expect to generate revenue from product sales for the foreseeable future.

Research and Development Expense

R&D expenses include, but are not limited to, third-party CRO arrangements and employee-related expenses, including salaries, benefits, stock-based compensation, and travel expense reimbursement. R&D activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical studies.

General and Administrative Expense

G&A expenses consist principally of salaries and related costs for executive and other personnel, including stock-based compensation, other employee benefit costs, expenses associated with investment bank and other financial advisory services, and travel expenses. Other G&A expenses include facility-related costs, communication expenses and professional fees for legal, patent prosecution and maintenance, consulting, accounting, and other professional services.

Interest Income

Interest income consists of interest earned from Diffusion's cash, cash equivalents and marketable securities.

Income Tax Benefit

Diffusion recorded no income tax benefit or expense during the year ended December 31, 2022. Diffusion maintains a full valuation allowance against its deferred tax assets due to the Company's history of losses as of December 31, 2022. Diffusion maintains a full valuation allowance against its deferred tax assets due to Diffusion's history of losses as of December 31, 2022.

Diffusion's net operating losses, or NOLs, and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of a greater than 50.0% cumulative change in the ownership interest of significant stockholders over a three-year period, as defined under Sections 382 and 383 of the Code, as well as similar state provisions. The amount of the annual limitation is determined based on the Diffusion's value immediately prior to the ownership change, and subsequent ownership changes may further affect the limitation in future years. In 2019, due to the significant changes to Diffusion's stockholder base as a result of the equity financing it completed during that year, Diffusion performed an analysis under Section 382 of the Code and, as a result, reduced the magnitude of its NOL carryforwards to account for the ownership changes. In addition, the cumulative benefit of Diffusion's NOLs was remeasured, resulting in tax expense recognized during the year ended December 31, 2019. Diffusion has not yet performed an analysis to determine whether or not ownership changes that have occurred in the year ended December 31, 2022 (or otherwise subsequent to the 2019 analysis) give rise to any further limitations.

Results of Operations for Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

The following table summarizes Diffusion's results of operations for the years ended December 31, 2022 and 2021:

	Year ended December 31,		Change
	2022	2021	
Operating expenses:			
Research and development	\$ 7,237,165	\$ 8,499,414	\$ (1,262,249)
Intangible asset impairment charge	—	8,639,000	\$ (8,639,000)
General and administrative	8,735,015	7,445,277	1,289,738
Depreciation	—	93,416	(93,416)
Loss from operations	(15,972,180)	(24,677,107)	(8,704,927)
Interest income	380,752	137,487	243,265
Loss from operations before income taxes	(15,591,428)	(24,539,620)	8,948,192
Income tax benefit	—	443,893	(443,893)
Net loss	<u>\$ (15,591,428)</u>	<u>\$ (24,095,727)</u>	<u>\$ 8,504,299</u>

Research and development expenses were \$7.2 million during the year ended December 31, 2022 compared to \$8.5 million during the year ended December 31, 2021, a decrease of 15%. This decrease was due to lower project spending due to the completion and/or wind-down of certain CMC-related activities and clinical studies evaluating TSC in Covid-19, GBM, and Diffusion's Oxygenation Trials.

The decrease in intangible asset impairment charge is related to the nonrecurring \$8.6 million non-cash impairment charge related to the write down of Diffusion's DFN-529 IPR&D asset during the year ended December 31, 2021.

General and administrative expenses were \$8.7 million during the year ended December 31, 2022 compared to \$7.4 million during the year ended December 31, 2021, an increase of 17%. The increase was primarily due to increased headcount resulting in higher compensation expense and other costs associated with the hiring of new employees as well as an increase in professional fees related to ongoing business development activity.

The decrease in depreciation for the year ended December 31, 2022 compared to the year ended December 31, 2021 is related to the disposal of property and equipment during the year-ended December 31, 2021 resulting in no remaining property and equipment remaining during the year ended December 31, 2022 for depreciating.

Interest income was \$0.4 million for the year ended December 31, 2022 compared to \$0.1 million for the year ended December 31, 2021 primarily as a result of investing a significant portion of Diffusion's cash balance in marketable securities during the second half of the year ended December 31, 2021 and rising interest rates during 2022.

The decrease in income tax benefit of \$0.4 million during the year ended December 31, 2022 compared to the year ended December 31, 2021 is due to the tax effect of the reduction in the deferred tax liability associated with the basis differences from the DFN-529 IPR&D intangible asset that was written down in the third quarter of 2021.

Liquidity and Capital Resources

Working Capital

The following table summarizes Diffusion's working capital as of December 31, 2022 and 2021:

	December 31,	
	2022	2021
Cash and cash equivalents	\$ 10,113,706	\$ 37,313,558
Marketable securities	12,408,940	—
Prepaid expenses, deposits and other assets	112,406	510,015
Total current liabilities	2,417,336	2,927,684
Working capital	<u>\$ 20,217,716</u>	<u>\$ 34,895,889</u>

Diffusion expects to continue to incur net losses for the foreseeable future. Diffusion intends to use its existing cash and cash equivalents for working capital purposes, to support its ongoing strategic review process and, subject to the outcome thereof, to fund the research and development of its product candidates.

Cash Flows

The following table sets forth Diffusion’s cash flows for the years ended December 31, 2022 and 2021:

	December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (14,969,114)	\$ (14,501,789)
Investing activities	(12,235,738)	4,000
Financing activities	5,000	33,295,752
Net (decrease) increase in cash and cash equivalents	<u>\$ (27,199,852)</u>	<u>\$ 18,797,963</u>

Operating Activities

For the year ended December 31, 2022, net cash used in operating activities increased \$0.5 million, or 3% compared to the year ended December 31, 2021.

Net cash used in operating activities of \$15.0 million during the year ended December 31, 2022 was primarily attributable to Diffusion’s net loss of \$15.6 million. These amounts were partially offset by Diffusion’s net change in operating assets and liabilities of \$0.1 million, and non-cash charges comprised of \$0.9 million of stock-based compensation expense, as well as \$0.2 million for the amortization of premium and discount on marketable securities.

Net cash used in operating activities of \$14.5 million during the year ended December 31, 2021 was primarily attributable to Diffusion’s net loss of \$24.1 million and a \$0.4 million change in deferred income taxes. These amounts were partially offset by a \$8.6 million non-cash impairment charge in connection with the write down of Diffusion’s DFN-529 IPR&D asset, Diffusion’s net change in operating assets and liabilities of \$0.4 million, and non-cash charges comprised of \$0.9 million of stock-based compensation expense and the loss on the write-off of property and equipment of \$0.1 million and depreciation expense of \$0.1 million.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2022 was attributable to the purchase of \$38.0 million of marketable securities and maturities of \$25.8 million of marketable securities. During the year ended December 31, 2021, Diffusion received \$4,000 from the sale of property and equipment.

Financing Activities

For the year ended December 31, 2022, net cash provided by financing activities decreased \$33.3 million, or 100% compared to the year ended December 31, 2021.

Net cash provided by financing activities of \$5,000 during the year ended December 31, 2022 was attributable to net proceeds received from the sale of Diffusion’s Series C Preferred Stock.

Net cash provided by financing activities of \$33.3 million during the year ended December 31, 2021 which was attributable to net proceeds of \$31.1 received from the sale of Diffusion Common Stock in connection with the February 2021 Offering and \$2.2 million in proceeds received from the exercise of previously issued common stock warrants.

Capital Requirements

Historically, including during the year ended December 31, 2022, Diffusion has incurred substantial expenses and generated significant operating losses pursuing its business strategy of developing TSC. As of the date of this proxy statement/prospectus/information statement and for the foreseeable future, most of Diffusion’s cash resources are dedicated to, and its planned expenditures are primarily related to, the Merger.

While Diffusion currently believes it has adequate cash resources to fund its current operations for at least 12 months following the completion of the Merger, Diffusion anticipates that it will likely need additional funding in the future to support its research and development activities and other operations which, if available, could be obtained through additional capital raising transactions, entry into strategic partnerships or collaborations, or alternative financing arrangements.

In July 2022, Diffusion entered into an At-The-Market Sales Agreement, dated July 22, 2022, with BTIG LLC, as agent (the “2022 Sales Agreement”). The 2022 Sales Agreement is an “at-the-market” sales agreement pursuant to which Diffusion may, from time to time and through BTIG as its agent, sell up to an aggregate of \$20.0 million in shares of Diffusion Common Stock by any permissible method deemed an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act. As of the date of this proxy statement/prospectus/information statement, however, Diffusion has not sold any shares pursuant to the 2022 Sales Agreement.

In the future, Diffusion may seek to raise additional funds through various sources. However, Diffusion can give no assurances that it will be able to secure additional sources of funds to support its operations, or if such funds are available to Diffusion, that such additional financing will be sufficient or be on terms acceptable to Diffusion. This risk may increase if economic and market conditions continue to be challenging or deteriorate. If Diffusion is unable to obtain additional financing when needed, we may need to curtail portions of its operations, terminate, significantly modify, or delay the development of its product candidates, or obtain funds on terms that may require Diffusion to relinquish rights to its technologies, product candidates or other assets that Diffusion might otherwise seek to develop or commercialize independently or receive superior value. If Diffusion is unable to raise adequate additional capital as and when required in the future, Diffusion could be forced to cease development activities and terminate its operations, and Diffusion stockholders could experience a complete loss of their investment.

To the extent that Diffusion raises additional capital in the future through the sale of Diffusion Common Stock or securities convertible or exchangeable for common stock such as common stock warrants, convertible preferred stock, or convertible debt instruments, or fund acquisitions or other transactions through the issuance of such securities, the interests of its current stockholders may be diluted or otherwise impacted. In particular, specific rights granted to future holders of preferred stock or convertible debt securities may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on Diffusion's ability to merge with or sell our assets to a third party. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

Diffusion does not have any off-balance sheet arrangements, as defined by the rules and regulations of the SEC that have or are reasonably likely to have a material effect on Diffusion's financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, Diffusion is not materially exposed to any financing, liquidity, market or credit risk that could arise if Diffusion had engaged in these arrangements.

Critical Accounting Policies and Estimates

Certain of Diffusion's critical accounting policies require estimates that involve the application of significant judgment by management in selecting the appropriate assumptions in determining the estimate. By their nature, these judgments are subject to an inherent degree of uncertainty. Diffusion develops these judgments based on historical experience, terms of existing contracts, observance of trends in the industry, and information available from other outside sources, as appropriate. Actual results may differ from these judgments under different assumptions or conditions, and different, reasonable estimates could have been used for the periods presented. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition, or results of operations. Diffusion believes the accounting policies described below are among the most critical to aid in fully understanding and evaluating its historical financial statements, as they required estimates which involve its most subjective or complex judgments.

Intangible Asset

Diffusion's sole intangible asset as of December 31, 2020 consisted of DFN-529, which was acquired in 2016 pursuant to Diffusion's merger with RestorGenex Corporation and was accounted for as an IPR&D intangible asset. The fair value of the IPR&D asset was determined as of the acquisition date using the cost approach, often referred to as current replacement cost, which establishes a value based on the cost of reproducing or replacing the asset. The cost approach was chosen as Diffusion was not able to estimate an income stream attributable to the IPR&D asset, given the fact that the related products had only completed limited preclinical and clinical trials and the timeline to commercial viability, if the FDA approval process were to be successful, was uncertain, would take a number of years, and the costs would have been significant.

In the third quarter of 2021, the Diffusion board of directors made a determination to no longer dedicate financial resources to its DFN-529 intangible asset and any future internal development efforts were abandoned. In connection with this decision, Diffusion concluded that DFN-529 was impaired in its entirety and as such, Diffusion recognized a non-cash impairment charge of \$8.6 million during the third quarter of 2021. The abandonment also resulted in an income tax benefit of \$0.4 million due to the tax effect of the reduction in the deferred tax liability associated with the asset.

Recently Issued Accounting Pronouncements

Diffusion's significant accounting policies are described in more detail in Note 3, Basis of Presentation and Summary of Significant Accounting Policies, in the notes to its consolidated financial statements as of and for the years ended December 31, 2022 and 2021, appearing elsewhere in this proxy statement/prospectus/information statement.

EIP MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless the context otherwise requires, all references in this section to “we,” “our,” “us,” “EIP” or “EIP Pharma” refer to the business of EIP Pharma, Inc. prior to the consummation of the Merger.

You should read the following discussion and analysis of our financial condition and results of operations together with the section titled “Unaudited Pro Forma Condensed Combined Financial Information” and our financial statements and related notes appearing elsewhere in this proxy statement/prospectus/information statement. This discussion and other parts of this proxy statement/prospectus/information statement contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the “Risk Factors” section of this proxy statement/prospectus/information statement, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section titled “Cautionary Statement Concerning Forward-looking Statements.”

Overview

We are a clinical stage CNS therapeutics company that is developing treatments for acute and chronic neurodegenerative diseases, such as DLB, and other neurologic indications. In DLB, for which there are no approved therapies and no disease-modifying drugs in Phase 3 clinical development, we believe we are one of the leaders in the industry, as we are the only company that we are aware of with an asset that, in that disease, has shown statistically significant positive effects compared to placebo in a Phase 2a clinical trial and is about to enter late-stage (Phase 2b) clinical evaluation. Our novel approach focuses on reducing the impact of inflammation in the brain, or neuroinflammation, which we believe is a key factor in the manifestation of neurodegenerative disease. Chronic activation of the enzyme p38 α in the neurons (nerve cells) within the brains of people with neurodegenerative diseases is believed to impair how neurons communicate through synapses (the connections between neurons). This impairment, termed synaptic dysfunction, leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in neuronal loss that leads to devastating disabilities, institutionalization and, ultimately, death. We believe that inhibiting p38 α in the brain, by interfering with key pathogenic drivers of disease, has the potential to improve cognitive and motor function observed in early stage neurodegenerative diseases. We also believe it is possible to modify the course of these diseases by delaying permanent synaptic dysfunction and neuron death.

We are developing an oral therapy, neflamapimod, that penetrates the blood-brain barrier and inhibits activity of p38 α in the neuron. Based on preclinical and clinical work to date, we believe if neflamapimod is given in the early stages of neurodegenerative diseases, it may reverse synaptic dysfunction and improve neuron health. In preclinical studies, neflamapimod has been shown to reverse the neurodegenerative process in the BFC system, the specific region of the brain that is the site of the major pathology in DLB. We have obtained positive Phase 2a clinical data in DLB, specifically, statistically significant improvement compared to placebo on measures of dementia severity and functional mobility (walking ability). In addition, we previously obtained and our Phase 2 clinical data in AD that provides supportive clinical data demonstrating blood-brain-barrier penetration, target engagement, and identifying dose-response.

Our next step in the clinical development of neflamapimod is the conduct of a Phase 2b placebo-controlled 160-subject clinical trial intended to confirm the Phase 2a results and provide the data necessary to finalize design of a Phase 3 clinical trial, the general framework of which has been agreed upon with the FDA. The Phase 2b trial is estimated to be fully funded by an awarded grant from the NIA and is planned to be initiated by the end of the second quarter of 2023, with data-readout in the second half of 2024.

To date, we have not had any products approved for sale and have not generated any revenue from product sales. We do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our product candidates. We have never been profitable, and we will continue to require additional capital to develop neflamapimod and fund operations for the foreseeable future. We have incurred net losses in each year since inception and expect to continue to incur net losses for the foreseeable future. Our ability to generate product revenue will depend on the successful development and eventual commercialization of neflamapimod. Our net losses were \$5.8 million and \$4.1 million for the years ended December 31, 2022, and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$52.3 million. Substantially all our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our expenses will increase in connection with our ongoing activities, as we:

- advance neflamapimod through clinical trials, including a Phase 2b trial for DLB, through to initiation of a Phase 3 trial in DLB in the first half of 2025;
- hire additional personnel;
- operate as a public company;
- require the manufacture of supplies for our nonclinical studies and clinical trials; and
- obtain, maintain, expand, and protect our intellectual property portfolio.

Our operations have been financed primarily through the sale of equity (preferred shares and common stock) to private investors and the issuance of convertible debt.

Our losses from operations and accumulated deficit, as well as the additional capital needed to fund operations within one year of the date of issuance of our audited financial statements raise substantial doubt about our ability to continue as a going concern. We expect to incur substantial expenditures in the foreseeable future for the development of neflamapimod and will require additional financing to continue this development. Our audited financial statements appearing elsewhere in this proxy statement/prospectus/information statement have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our audited financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Merger Agreement

On March 30, 2023, we entered into the Merger Agreement with Diffusion. The Merger will result in our becoming a publicly traded company under the name “CervoMed, Inc.” The Merger is expected to close in mid-2023.

Impact of COVID

The COVID-19 pandemic continues to evolve. While it appears its most severe effects have subsided, COVID-19 could re-emerge or new public health threats could appear. The future impact of the COVID-19 pandemic or a similar health disruption is highly uncertain and subject to change. We cannot predict the full extent of potential delays or impacts on our business, our clinical trials, health care systems, third parties with whom we engage or the global economy as a whole, but if we or any of the third parties with whom we engage, including personnel at CMOs and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. Overall, we recognize the challenges of product development during a pandemic, and we will continue to closely monitor events as they develop and plan for alternative and mitigating measures if needed.

Components of Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future. We expect to generate revenue in the future in connection with activities funded pursuant to the NIA grant.

Research and Development Expenses

Research and development expenses account for a significant portion of our operating expenses. We recognize research and development expenses as incurred. Research and development expenses consist primarily of costs incurred for the discovery and development of our product candidates, which include:

- expenses incurred under agreements with third-party contract organizations, preclinical testing organizations, and consultants;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- vendor expenses related to the execution of preclinical studies and clinical trials;
- personnel-related expenses, including salaries, benefits, and stock-based compensation for personnel engaged in research and development functions;
- costs related to the preparation of regulatory submissions;
- third-party license fees; and
- expenses for rent and other supplies.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators, and third-party service providers. Non-refundable advance payments made by the Company for future research and development activities are capitalized and expensed as the related goods are delivered and as services are performed.

Specific program expenses include expenses associated with the development of our lead product candidate, neflamapimod, which is entering a Phase 2b clinical trial for treatment of subjects with DLB. Personnel or other operating expenses incurred for our research and development programs primarily relate to salaries and benefits, stock-based compensation, and facility expenses.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, neflamapimod, or for any other product candidates that we may develop or acquire. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in R&D activities related to developing neflamapimod such as conducting larger clinical trials, seeking regulatory approval and incurring expenses associated with hiring personnel to support other R&D efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of product candidates, including neflamapimod, is highly uncertain.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for our personnel in executive, finance and accounting, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, consulting, and tax services, insurance costs, and facility costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities and as we begin development activities pursuant to the NIA grant. We also anticipate that we will incur increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services.

Other Income (Expense)

Other income (expense) consists of interest earned on our cash and cash equivalents, the forgiveness of our Paycheck Protection Program loan, and the change in fair value of the convertible notes issued in 2021, (the "2021 Notes") and in 2020 (the "2020 Notes").

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

Comparison of Years Ended December 31, 2022 and 2021

	Year ended December 31,		Change	
	2022	2021	\$	%
Operating expenses				
Research and development	\$ 1,336,469	\$ 2,421,593	\$ (1,085,124)	(45)%
General and administrative	2,139,065	2,615,520	(476,455)	(18)%
Total Operating Expenses	<u>3,475,534</u>	<u>5,037,113</u>	<u>1,561,579</u>	31%
Loss from operations	(3,475,534)	(5,037,113)	1,561,579	31%
Other income (expense)				
Other income (expense)	(2,389,152)	882,254	(3,271,406)	(371)%
Interest income	62,226	19,854	42,372	213%
Interest expense	(587)	(429)	(158)	(37)%
Total other income (expense)	<u>(2,327,513)</u>	<u>901,679</u>	<u>(3,229,192)</u>	<u>(358)%</u>
Net loss	<u>\$ (5,803,047)</u>	<u>\$ (4,135,434)</u>	<u>\$ (1,667,613)</u>	<u>(40)%</u>

Research and Development Expenses

Research and development expenses were \$1.3 million for the year ended December 31, 2022, compared to \$2.4 million for the year ended December 31, 2021. The decrease of \$1.1 million was primarily driven by reduced clinical trial activity.

General and Administrative Expenses

General and administrative expenses were \$2.1 million for the year ended December 31, 2022, compared to \$2.6 million for the year ended December 31, 2021. The decrease of \$0.5 million was primarily due to a decrease in personnel costs due to a reduction in headcount of \$0.1 million, a decrease in non-cash stock-based compensation of \$0.3 million and a decrease in other general and administrative expense of \$0.1 million.

Other Income (expense)

Other income (expense) was \$(2.4 million) for the year ended December 31, 2022, compared to \$0.9 million for the year ended December 31, 2021. There was a \$2.4 million adjustment in fair value of the 2021 Notes and the 2020 Notes during the year ended December 31, 2022. There was a \$0.7 million adjustment in fair value of the 2021 Notes and the 2020 Notes and a \$0.2 million gain on extinguishment of the PPP loan during the year ended December 31, 2021. For more information on the 2021 Notes and the 2020 Notes, see Note 9 to the Company's financial statements for the year ended December 31, 2022, included elsewhere in this proxy statement/prospectus/in formation statement.

Interest Income

Interest income, was \$62,226 for the year ended December 31, 2022, compared to \$19,854 for the year ended December 31, 2021. The increase of \$42,372 was due to higher interest rates during the year ended December 31, 2022.

Interest expense

Interest expense was \$587 for the year ended December 31, 2022, compared to \$429 for the year ended December 31, 2021.

Liquidity and Capital Resources

Sources of Liquidity

From the date of our inception through December 31, 2022, our operations have been financed primarily through the issuance of common stock, convertible preferred stock and convertible debt financings. As of December 31, 2022, we had approximately \$4.1 million of cash and cash equivalents. We have incurred net operating losses since inception and have not generated positive cash flows from operations. As of December 31, 2022 and 2021, we had an accumulated deficit of approximately \$52.3 million and \$46.5 million, respectively. In January 2023, we were awarded a \$21.0 million grant from the NIA to support our Phase 2b study of neflamapimod in DLB, which is expected to be received over a three-year period. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our convertible debt totaling \$12.4 million becomes due in December 2023. Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations within one year of the audited financial statement issuance date, raise substantial doubt about our ability to continue as a going concern. We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates and will require additional financing to continue this development. The audited financial statements appearing elsewhere in this proxy statement/prospectus/information statement have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The audited financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Future Funding Requirements

Any product candidates we may develop may never achieve commercialization, and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In addition, upon the completion of the Merger, we expect to incur additional costs associated with operating as a public company. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, costs related to clinical research, manufacturing and development services; compensation and related expenses; costs relating to the build-out of our headquarters, other offices and laboratories; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; manufacturing costs; legal and other regulatory expenses and general overhead costs.

Based on our current operating plan, we believe that our existing cash and cash equivalents on hand, along with the \$21.0 million grant from the NIA and minimum cash of \$12.0 million required to be delivered by Diffusion in the Merger, as well as conversion of the EIP Convertible Notes into EIP Common Stock (rather than paid out to the holders), will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the date of this proxy statement/prospectus/information statement. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs, including our development or commercialization activities for neflamapimod. We might also be required to seek funds through arrangements with third parties that require us to relinquish certain of our rights to neflamapimod or otherwise agree to terms unfavorable to us.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the initiation, progress, timing, costs and results of a proposed Phase 2b trial for neflamapimod in patients with DLB, as well as additional development plans for neflamapimod in other disease indications, such as Recovery after Anterior Circulation Ischemic Stroke and EOAD;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- our ability to reach certain milestone events set forth in our collaboration agreements and the timing of such achievements, triggering our obligation to make applicable payments;
- the hiring of additional clinical, scientific and commercial personnel to pursue our development plans, as well the increased costs of internal and external resources as to support our transition to a public reporting company;
- the cost and timing of securing manufacturing arrangements for clinical or commercial production;
- the cost of establishing, either internally or in collaboration with others, sales, marketing and distribution capabilities to commercialize neflamapimod, if approved;
- the cost of filing, prosecuting, enforcing, and defending our patent claims and other intellectual property rights, including defending against any patent infringement actions brought by third parties against us;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- our ability to establish strategic collaborations, licensing or other arrangements with other parties on favorable terms, if at all; and
- the extent to which we may in-license or acquire other product candidates or technologies.

A change in the outcome of any of these or other variables with respect to the development of neflamapimod could significantly change the costs and timing associated with the development of neflamapimod. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Cash Flows

The following table summarizes our cash flows of the periods indicated:

	Year ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (2,572,759)	\$ (4,134,535)
Financing activities	-	6,000,000
Net increase (decrease) in cash and cash equivalents	<u>\$ (2,572,759)</u>	<u>\$ 1,865,465</u>

Net Cash Used in Operating Activities

For the year ended December 31, 2022, cash used in operating activities was \$2.6 million. The net cash outflow from operations primarily resulted from net loss of \$5.8 million, offset by a non-cash charge of \$0.3 million for stock-based compensation, contributed capital in lieu of executive compensation of \$0.1 million, change in fair value of convertible debt of \$2.4 million and a change in operating assets and liabilities of \$0.4 million.

For the year ended December 31, 2021, cash used in operating activities was \$4.1 million. The net cash outflow from operations primarily resulted from net loss of \$4.1 million, change in fair value of convertible debt of \$0.7 million, gain of extinguishment of PPP loan of \$0.1 million and a change in operating assets and liabilities of \$0.1 million, partially offset by a non-cash charge of \$0.7 million for stock-based compensation and contributed capital in lieu of executive compensation of \$0.3 million.

Net Cash Provided by Financing Activities

During the year ended December 31, 2022, the Company did not have any cash provided by financing activities.

During the year ended December 31, 2021, cash provided by financing activities was \$6.0 million, primarily from the issuance of the 2021 Notes.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, non-clinical studies and manufacturing, and other services for operating purposes. The amount and timing of contractual obligations may vary based on the timing of services.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. We believe the following are our more significant estimates and judgments used in the preparation of our financial statements.

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of new product development. Research and development costs include salaries and benefits, consultants' fees, process development costs and stock-based compensation, as well as fees paid to third parties that conduct certain research and development activities on our behalf.

A substantial portion of our ongoing research and development activities are conducted by third-party service providers. We record accrued expenses for estimated preclinical study and clinical trial expenses. Estimates are based on the services performed pursuant to contracts with research institutions, contract research organizations in connection with clinical studies, investigative sites in connection with clinical studies, vendors in connection with preclinical development activities, and contract manufacturing organizations in connection with the production of materials for clinical trials. Further, we accrue expenses related to clinical trials based on the level of subject enrollment and activity according to the related agreement. We monitor subject enrollment levels and related activity to the extent reasonably possible and make judgments and estimates in determining the accrued balance in each reporting period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development.

If we underestimate or overestimate the level of services performed or the costs of these services, actual expenses could differ from estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

Stock-based Compensation

Stock-based compensation for employee and non-employee awards is measured on the grant date based on the fair value of the award and recognized on a straight-line basis over the requisite service period. The fair value of stock options to purchase common stock are measured using the Black-Scholes option pricing model. We account for forfeitures as they occur. The fair value of stock options is determined by us using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

Expected Term. The expected term represents the period that stock-based awards are expected to be outstanding. We use the "simplified method" to estimate the expected term of stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of our stock options, taking into consideration multiple vesting tranches. We utilize this method due to lack of historical data and the plain-vanilla nature of our stock-based awards.

Expected Volatility. We have limited information on the volatility of common stock as the shares are not actively traded on any public markets. The expected volatility is derived from the historical stock volatilities of comparable peer public companies within its industry. These companies are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the and stock options expected term.

Expected Dividend Rate. The expected dividend is zero as we have not paid, nor do we anticipate paying, any dividends on our stock options in the foreseeable future

Prior to the date of this proxy statement/prospectus/information statement, the grant date fair value of our common stock was typically determined by our board of directors with the assistance of management and a third-party valuation specialist. For valuations after the completion of the Merger, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to recover or settle. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income for the period that includes the enactment date.

The deferred tax assets are recognized to the extent we believe that these assets are more likely than not to be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to our historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

We record uncertain tax positions using a two-step process. First, we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position. Second, for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

We recognize interest and penalties related to unrecognized tax benefits on the interest expense line and other expense line, respectively, in the accompanying statements of operations. Accrued interest and penalties are included on the related liability lines in the balance sheet.

Valuation of Convertible Notes

The fair value of the 2020 Notes and the 2021 Notes as of December 31, 2022, and the fair value of the 2021 Notes as of December 31, 2021, are estimated as the combination of a zero-coupon bond and a call option. The combined values for each of the 2020 Notes and the 2021 Notes as of December 31, 2022 have been weighted by the probability of completing a financing or reverse merger, while the combined value for the 2021 Notes as of December 31, 2021 has been weighted by the probability of completing a financing. The assumptions utilized to value the 2020 Notes and the 2021 Notes as of December 31, 2022 use an estimated term of 0.94 years, volatility of 80.0% and a market yield of 55.2%. The assumptions utilized to value the 2021 Notes as of December 31, 2021 are an estimated term of 1.94 years, volatility of 81.0% and a market yield of 45.2%. The measurement of fair value incorporates expected future cash flows associated with interest payments; as such, there is no separate accrual for interest accrued but not yet paid.

Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk.

We had cash and cash equivalents of \$4.1 million and \$6.7 million as of December 31, 2022 and December 31, 2021, respectively, which included bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk. However, historical fluctuations in interest income have not been significant for us.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services with payments denominated in foreign currencies, including the Euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency.

Effects of Inflation

We believe that inflation and changing prices have had a moderate impact on our results of operations for the period presented herein.

Recently Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in the notes to our financial statements appearing elsewhere in this proxy statement/prospectus/information statement.

MANAGEMENT FOLLOWING THE MERGER**Executive Officers and Directors of the Combined Company Following the Merger**

Pursuant to the Merger Agreement, four of the six current directors of Diffusion will resign at or prior to the Effective Time. Effective at the Effective Time, five designees selected by EIP will be appointed to serve as members of the combined company's board of directors. Collectively, the reconstituted board is expected to satisfy the requisite independence requirements for the Diffusion board of directors, as well as the sophistication and independence requirements for the required committees pursuant to Nasdaq listing requirements.

The following table lists the names, ages as of April 1, 2023, and positions of the individuals who are expected to serve as executive officers and directors of the combined company upon the completion of the Merger:

Name	Age	Position(s)	Pre-Merger Position(s)
<i>Executive Officers</i>			
John Alam, MD	61	Chief Executive Officer	President and Chief Executive Officer (EIP)
Robert J. Cobuzzi, Jr., Ph.D	58	Chief Operating Officer	President and Chief Executive Officer (Diffusion)
William Tanner, Ph.D	64	Chief Financial Officer	Chief Financial Officer (EIP)
Kelly Blackburn, MHA	59	Senior Vice President, Clinical Development	Senior Vice President (EIP)
William Elder	40	General Counsel and Corporate Secretary	General Counsel and Corporate Secretary (Diffusion)
<i>Non-Employee Directors</i>			
Sylvie Grégoire, PharmD	61	Director and Chair	Director and Chair (EIP)
Jeff Poulton	55	Director	Director (EIP)
Jane Hollingsworth, JD	65	Director	Director and Chair (Diffusion)
Frank Zavrl	57	Director	Director (EIP)
Dr. Marwan Sabbagh, MD	57	Director	Director (EIP)

Executive Officers and Employee Directors**John Alam, MD**

Dr. Alam is EIP's co-founder and has served as EIP's President and Chief Executive Officer and as a member of EIP's board of directors since April 2018. Prior to that, Dr. Alam served as a managing member of EIP Pharma, LLC, EIP's predecessor entity, from its inception in 2010. From January 2011 to August 2014, Dr. Alam served as therapeutic area head for diseases of aging at Sanofi S.A. (NASDAQ: SNY), a global pharmaceutical company. From 1997 until 2008, he held positions of increasing responsibility at Vertex Pharmaceuticals Incorporated (NASDAQ: VRTX), most recently as Chief Medical Officer and Executive Vice President, Medicines Development. From 1991 to 1997, Dr. Alam worked at Biogen Inc. (NASDAQ: BIIB), where he led the clinical development of Avonex, a drug that treats multiple sclerosis. From 2014 to 2022, Dr. Alam served as a member of the board of directors of the Alliance for Aging Research, a non-profit organization dedicated to promoting innovation to address the healthcare needs of older Americans. Dr. Alam received an S.B. in chemical engineering from the Massachusetts Institute of Technology and a M.D. from Northwestern University School of Medicine. Dr. Alam completed an internal medicine residency at Brigham and Women's Hospital and a post-doctoral fellowship at Dana-Farber Cancer Institute. Diffusion and EIP believe Dr. Alam is qualified to serve on the combined company's board of directors due to his service as EIP's president and chief executive officer, and his extensive knowledge of our company and significant background in pharmaceutical research and development.

Robert J. Cobuzzi, Jr., Ph.D.

Dr. Cobuzzi has served as a director of Diffusion since January 2020 and as its President and Chief Executive Officer since September 2020. Dr. Cobuzzi also currently serves as a Venture Partner and Chairman of the Business Development Board for Sunstone Life Science Ventures, an independent European venture capital investment firm focused on life science therapeutic innovations. Previously, Dr. Cobuzzi served as an Advisor to the Mitochondrial Disease Research Program at the Children’s Hospital of Philadelphia, an internationally recognized hospital and research center devoted to children, from January 2019 to April 2020, and as President and Chief Executive Officer of MitoCUREia, Inc., an affiliated company, from July 2019 to July 2020. From 2005 to 2018, Dr. Cobuzzi served in various roles at Endo International PLC, a specialty branded and generic pharmaceuticals manufacturer, most recently serving as President of Endo Ventures Limited. Dr. Cobuzzi received his Bachelor of Arts in Biochemistry and Art History from Colby College and his Ph.D. in Molecular and Cellular Biochemistry from Loyola University Chicago. He served as a Post-doctoral Fellow in Experimental Therapeutics at Roswell Park Cancer Institute.

Diffusion and EIP believe Dr. Cobuzzi’s experience and insight with drug development and business development and funding, both in the U.S. and abroad, as well as his experience and background as Diffusion’s Chief Executive Officer, provide him with the qualifications to serve on the combined company’s board of directors.

William Tanner, Ph.D

Dr. Tanner has served as EIP’s Chief Financial Officer since September 2022. Dr. Tanner has been a Managing Director at Danforth Advisors, a financial and operational company for outsourced corporate and clinical business functions, since April 2022 and previously served as the chief financial officer of Danforth Advisors from November 2021 to April 2022. He co-founded ImmunoGenesis, Inc., a clinical stage immuno-oncology company, in May 2019 and served as its chief financial officer until October 2021. From November 2022 to April 2023, Dr. Tanner served as the chief financial officer of siRNAgen Therapeutics and from May 2021 to April 2023, he served as the interim chief financial officer of Synthis Therapeutics, Inc. Prior to that, Dr. Tanner was a managing director at Brookline Capital Markets from April 2019 to May 2019, an analyst at Cantor Fitzgerald & Co. from November 2016 to November 2018, and an analyst at Guggenheim Securities from May 2015 to November 2016. Dr. Tanner earned his B.S. and Ph.D. in physiology from Texas A&M University and completed post-doctoral training in Washington University School of Medicine’s Department of Cell Biology and in the Center for Immunology. He received his MBA from Washington University’s Olin Business School.

Kelly Blackburn, MHA

Ms. Blackburn has served as Senior Vice President, Clinical Development of EIP since May 2018. Previously, Ms. Blackburn served as Vice President, Clinical Affairs of aTyr Pharma, Inc. (NASDAQ: LIFE) from July 2013 to July 2016. Ms. Blackburn served as a clinical development consultant from September 2012 to July 2013 to a number of companies, including Agios Pharmaceuticals, Promedior Inc. and aTyr Pharma. Prior to this, Ms. Blackburn was the Vice President, Clinical Development Operations at Vertex Pharmaceuticals Incorporated (NASDAQ: VRTX), a global biotechnology company, from September 2006 to September 2012 overseeing programs for Incivek, Kalydeco as well as their early development programs. From September 2002 to August 2006, Ms. Blackburn was Director of Clinical and Safety Operations for Millennium Pharmaceuticals where she was responsible for the VELCADE program which was successfully approved during her tenure. Ms. Blackburn holds a B.S. in biochemistry from University of New Hampshire, an M.H.A. from Quinnipiac College and a M.Ed. from Cambridge College.

William Elder

Mr. Elder has served as Diffusion's General Counsel & Corporate Secretary since September 2020. Prior to joining Diffusion, Mr. Elder principally served as president and chief executive officer of BillyVonElds, LLC, a season-long and daily fantasy sports company, where he managed all corporate, legal, and operational aspects of the business from April 2019 to September 2020. From July 2020 to September 2020, Mr. Elder also served as a part-time consultant to Diffusion. From 2011 to February 2019, Mr. Elder served as a corporate and securities associate for Dechert LLP, an international law firm, where Mr. Elder's practice focused primarily on counseling public companies on securities laws and regulatory requirements, corporate governance matters, and financial transactions in the equity and debt markets. He received his J.D. from the University of Pennsylvania Law School, an M.S. in finance from Villanova University, and a B.A. in economics from Tufts University.

Non-Employee Directors

Sylvie Grégoire, PharmD

Dr. Grégoire is EIP's co-founder and has served as EIP's Executive Chair and as a member of EIP's board of directors since April 2018. From May 2013 to May 2019, Dr. Grégoire served as a director for Vifor Pharma AG (SIX: VIFN), a global pharmaceutical company focused on treatments for renal disease. From September 2007 to May 2013, Dr. Grégoire served as President of the Human Genetic Therapies division of Shire plc, a global biopharmaceutical company recently acquired by Takeda Pharmaceutical Company Limited. From 2005 to 2008, she served as a director of IDM Pharma, Inc., a publicly traded biotechnology company that now operates as a subsidiary of Takeda Pharmaceuticals Company Limited, including serving as its Executive Chair from August 2006 to October 2007. From 2004 to 2005, Dr. Grégoire served as President, Chief Executive Officer and Executive Member of the board of directors of GlycoFi, Inc., a private biotechnology company now part of Merck and Co., Inc. Prior to that, Dr. Grégoire held various leadership positions at Biogen, Inc. (NASDAQ: BIIB), including Vice-President (head) of Regulatory Affairs, Vice-President (head) of Manufacturing, and as Executive Vice President of Technical Operations. Dr. Grégoire also served at Merck and Co., Inc. in the US and internationally in clinical research and regulatory affairs. Dr. Grégoire serves on the board of directors of Novo Nordisk A/S (NYSE: NVO), a global pharmaceutical company, where she sits on the audit committee, the nomination committee and the research and development committee. Dr. Grégoire has also serves on the board of directors of Revvity Inc (NASDAQ: RVTY) (previously PerkinElmer, Inc. (NYSE: PKI)), a publicly traded company and a provider of products, services and solutions for the diagnostics, life sciences and applied markets, since February 2015. At Revvity, she also serves on the compensation and benefits committee and the nominating and corporate governance committee. In addition, Dr. Grégoire served as chair of the board of directors of Corvidia Therapeutics, Inc., from 2016 to 2020, a private company focused on treatments for cardio-renal diseases. Corvidia was sold to NovoNordisk in 2020. Dr. Grégoire serves on the board of F2G Ltd, a privately held company developing treatments for severe rare mold infections since December 2021 where she is also the chair of the Commercial Committee. Dr. Grégoire received a bachelor's degree in Pharmacy from Laval University and a doctoral degree in Pharmacy from the State University of New York at Buffalo. Diffusion and EIP believe Dr. Grégoire is qualified to serve on the combined company's board of directors due to her management experience in the pharmaceutical and biotechnology sector and her broad experience of service on other boards of directors.

Jeff Poulton

Mr. Poulton has been a member of EIP's board of directors since April 2018. Since July 2019, Mr. Poulton has served as Chief Financial Officer at Alnylam Pharmaceuticals, Inc. (NASDAQ: ALNY), a global biopharmaceutical company based in Cambridge, Massachusetts. From January 2018 to April 2019, Mr. Poulton served as chief financial officer at Indigo Agriculture, a plant microbiome company. From September 1998 to December 2017, Mr. Poulton held various roles of increasing responsibility at Shire plc, a biotechnology company, culminating in his service as chief financial officer from July 2014 to December 2017 and a member of Shire's executive committee and board of directors from January 2015 to December 2017. During his tenure at Shire, Mr. Poulton also lead Shire's rare disease US/APAC and LATAM commercial operations, as well as Shire's rare disease business unit. Prior to his tenure at Shire, Mr. Poulton led corporate finance and business development initiatives in both the gas and electric utilities industry and the materials manufacturing sector, serving in financial leadership positions at Cinergy Corporation and PPG Industries, Inc. Mr. Poulton also served as a U.S. Navy Commissioned Officer aboard the USS Peoria. Mr. Poulton holds a B.A. in Economics from Duke University and an MBA in Finance from the Kelly School of Business at Indiana University. Diffusion and EIP believe Mr. Poulton is qualified to serve on the combined company's board of directors due to his significant financial and operational experience in the life sciences industry.

Jane H. Hollingsworth

Ms. Hollingsworth has served as a director of Diffusion and as Chair of Diffusion's board of directors since September 2020. She currently serves as the founding Managing Partner of Militia Hill Ventures, an organization that creates, builds, and invests in life sciences companies, a role she has held since 2013. While at Militia Hill, Jane co-founded and currently serves as Executive Chair of Elikxa Therapeutics, a regenerative medicine company, co-founded and served as Executive Chair of Spirovant Sciences, a gene therapy company sold to Sumitomo Dainippon Pharma, and served as Executive Chair and CEO of Immunome Inc. (NASDAQ: IMNM), a cancer immunotherapy company. Prior to founding Militia Hill, Ms. Hollingsworth co-founded and served as Chief Executive Officer of NuPathe, Inc., a neuroscience focused biopharmaceutical company. She also co-founded and served as EVP of Auxilium Pharmaceuticals, a urology and rare disease focused biopharmaceutical company. Ms. Hollingsworth also currently serves on the boards of the life science companies Afimmune Ltd. and Ribonova, and various industry and community organizations, including the University City Science Center, the Kimmel Center for the Performing Arts and Breatcancer.Org. Ms. Hollingsworth received her B.A. from Gettysburg College and her J.D. from Villanova University.

Ms. Hollingsworth is qualified to serve on the combined company's board of directors due to her industry perspective and experience, including as chief executive officer and director of a publicly-traded biopharmaceutical company, as well as her depth of her other operating and senior management experience in the industry and educational background.

Frank Zavrl

Mr. Zavrl has been a member of EIP's board of directors since April 2018. From September 2017 to March 2018, Mr. Zavrl served as a member of the board of directors of EIP Pharma, LLC. Prior to that, Mr. Zavrl has served on the board of directors of Puma Biotechnology, Inc. (NASDAQ: PBYI), a publicly-traded company focused on the treatment of cancer, from September 2015 to July 2020. From 2002 to 2011, Mr. Zavrl served as a Partner at Adage Capital Management, L.P., an asset management company, where Mr. Zavrl specialized in biotechnology investments. From 1999 to 2002, Mr. Zavrl served as a Portfolio Manager at Merlin BioMed Group, a healthcare investment firm. Previously, Mr. Zavrl served from 1998 to 1999 as an analyst at Scudder Kemper Investments Inc., focusing on biotechnology investments. Mr. Zavrl received a B.S. in Biochemistry from the University of California, Berkeley and an M.B.A. from the Tuck School of Business at Dartmouth College. Diffusion and EIP believe Mr. Zavrl is qualified to serve on the combined company's board of directors due to his significant investment experience in pharmaceutical and biotechnology companies.

Marwan Sabbagh, MD

Dr. Sabbagh has been a member of EIP's board of directors since November 2021. Since October 2021, Dr. Sabbagh has served as a professor in the Department of Neurology and recently became Vice Chairman for Research at the Barrow Neurological Institute and is board certified in neurology by the American Board of Psychiatry and Neurology. He is also a fellow of the American Academy of Neurology. Previously, from May 2018 to October 2021, Dr. Sabbagh was a neurologist and director at the Cleveland Clinic Lou Ruvo Center for Brain Health. Prior to his time at the Cleveland Clinic, Dr. Sabbagh was a director and neurologist at the Banner Sun Health Research Institute from 2000 to 2015. Dr. Sabbagh served on the board of directors of Quince Therapeutics, Inc. (f/k/a/ Cortexyme, Inc.) (NASDAQ: QNCX) from March 2022 to September 2022. Dr. Sabbagh earned his medical degree from the University of Arizona College of Medicine and his undergraduate degree from the University of California Berkeley. He completed his neurology residency at Baylor College of Medicine and a geriatric neurology and dementia fellowship at the University of California San Diego School of Medicine. Diffusion and EIP believe that Dr. Sabbagh is qualified to serve on the combined company's board of directors due to his expertise neurological diseases and extensive clinical development experience.

Family Relationships

John Alam, MD, and Sylvie Grégoire, PharmD, are husband and wife. Other than their relationship, there are no family relationships among any of the combined company's directors or executive officers.

Board Composition Following the Merger

Effective at the Effective Time, the combined company's board of directors will consist of seven directors. Diffusion's bylaws provide that directors are to be elected at each annual meeting of stockholders to hold office until the next annual meeting and until their respective successors are duly elected and qualified or until their earlier death, resignation, disqualification or removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless Diffusion's board of directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum of Diffusion's board of directors. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

Director Independence

Diffusion's board of directors undertook a review of the independence of the proposed directors of the combined company and considered whether any director has a material relationship with the combined company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, the board of directors has determined that all of the proposed directors, except Drs. Alam and Cobuzzi, of the combined company, is "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, Diffusion's board of directors considered the current and prior relationships that each non-employee director has with the combined company and all other facts and circumstances the board of directors deemed relevant in determining their independence, including the beneficial ownership of capital stock by each non-employee director, and the transactions involving them described in the section titled "*Certain Relationships and Related-Party Transactions*" beginning on page 270.

Board Composition and Diversity

Of all of the members of the combined company's board of directors, two members of the combined company's board of directors self-identified as female, no member of the combined company's board of directors self-identified as LGBTQ+, and one member of the combined company's board of directors self-identified as an Underrepresented Minority. EIP believes the board of directors will meet the diversity objectives of Nasdaq Listing Rule 5605(f) and the following table includes information on the diversity of the combined company's board of directors based upon information voluntarily provided by each director.

Board Diversity Matrix (As of April 1, 2023)**Total Number of Directors: 7**

	<u>Female</u>	<u>Male</u>	<u>Non-Binary</u>	<u>Did Not Disclose Gender</u>
Part I: Gender Identity				
Directors	2	5	0	0
Part II: Demographic Background				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	0	1	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	2	4	0	0
Two or More Races of Ethnicities	0	0	0	0
LGBTQ+	0	0	0	0
Did Not Disclose Demographic Background	0	0	0	0

Board Committees of the Combined Company's Board of Directors

The board of directors of the combined company will have the authority to appoint committees to perform certain management and administration functions. The Diffusion board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The board of directors of the combined company may establish other committees to facilitate the management of the combined company's business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by the board of directors.

All of the committees will comply with all applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations as further described below. Following the Effective Time, the charters for each of these committees will be available on the combined company's website at www.cervomed.com. Such charters are currently available on Diffusion's website at www.diffusionpharma.com. Information contained on or accessible through Diffusion's or EIP's website is not a part of this proxy statement/prospectus/information statement, and the inclusion of such website address in this proxy statement/prospectus/information statement is an inactive textual reference only.

Audit Committee*Responsibilities*

The Audit Committee of the combined company will retain the responsibilities of the Audit Committee of Diffusion's board of directors, which include:

- overseeing the combined company's accounting and financial reporting processes, systems of internal control over financial reporting and disclosure controls and procedures on behalf of the board of directors and reporting the results or findings of its oversight activities to the board of directors ;
- having sole authority to appoint, retain and oversee the work of the combined company's independent registered public accounting firm and establishing the compensation to be paid to the independent registered public accounting firm;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and/or auditing matters and for the confidential, anonymous submission by the combined company's employees of concerns regarding questionable accounting or auditing matters;
- reviewing and pre-approving all audit services and permissible non-audit services to be performed for the combined company by the combined company's independent registered public accounting firm as provided under the federal securities laws and rules and regulations of the SEC; and
- overseeing the combined company's system to monitor and manage risk, and legal and ethical compliance programs, including the establishment and administration (including the grant of any waiver from) a written code of ethics applicable to each of the combined company's principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions.

The Audit Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition and Audit Committee Financial Expert

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the Audit Committee. To qualify as independent to serve on the combined company's audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from the combined company, other than for service as a director, or be an affiliated person of the combined company. Diffusion and EIP believe that, after the completion of the Merger, the composition of the Audit Committee will meet the requirements for independence under, and the functioning of such Audit Committee will comply with, the Listing Rules of the Nasdaq Capital Market and Rule 10A-3(b)(1) of the Exchange Act.

Each member of the combined company's Audit Committee will qualify as "independent" for purposes of membership on audit committees under the Listing Rules of the Nasdaq Capital Market and the rules and regulations of the SEC and be "financially literate" under the Listing Rules of the Nasdaq Capital Market. In addition, the combined company's board of directors will determine which member(s) of the Audit Committee qualify as an "audit committee financial expert" as defined by the rules and regulations of the SEC and meets the qualifications of "financial sophistication" under the Listing Rules of the Nasdaq Capital Market as a result of such individual's experience in senior financial positions. Stockholders should understand that these designations related to the Audit Committee members' experience and understanding with respect to certain accounting and auditing matters are disclosure requirements of the SEC and the Nasdaq Capital Market and do not impose upon any of them any duties, obligations or liabilities that are greater than those generally imposed on a member of the Audit Committee or of the board of directors of the combined company.

Processes and Procedures for Complaints

The Audit Committee of the combined company's board of directors is expected to retain the procedures of the Audit Committee of Diffusion's board of directors for the receipt, retention and treatment of complaints Diffusion receives regarding accounting, internal accounting controls, or auditing matters, and the submission by its employees, on a confidential and anonymous basis, of concerns regarding questionable accounting or auditing matters. The combined company's personnel with such concerns will be encouraged to discuss their concerns with their supervisor first, who in turn will be responsible for informing the Chief Executive Officer of any concerns raised. If an employee prefers not to discuss a particular matter with his or her own supervisor, the employee may instead discuss such matter with the Chief Executive Officer. If an individual prefers not to discuss a matter with the Chief Executive Officer or if the Chief Executive Officer is unavailable and the matter is urgent, the individual is encouraged to contact the Chair of the Audit Committee.

Diffusion and EIP believe that, after the completion of the Merger, the composition of the Audit Committee will meet the requirements for independence under, and the Audit Committee will comply with, any applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Committee

Responsibilities

The Compensation Committee of the combined company will retain the responsibilities of the Compensation Committee of Diffusion's board of directors, which include:

- determining the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to the Chief Executive Officer and other executive officers;
- determining any revisions to corporate goals and objectives with respect to compensation for the Chief Executive Officer and other executive officers and establishing and leading a process for the full Board to evaluate the performance of the Chief Executive Officer and other executive officers in light of those goals and objectives;
- administering the equity-based compensation plans, including determining specific grants of options and other awards for executive officers and other employees under Diffusion's equity-based compensation plans; and
- establishing and leading a process for determination of the compensation applicable to the non-employee directors on Diffusion's board of directors.

The Compensation Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the Compensation Committee. Diffusion and EIP believe that each member of the combined company's Compensation Committee will satisfy the independence requirements under the Listing Rules of the Nasdaq Capital Market and be a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act.

Processes and Procedures for Consideration and Determination of Executive Compensation

The Compensation Committee of the combined company's board of directors is expected to retain the processes and procedures of the Compensation Committee of Diffusion's board of directors for consideration and determination of director compensation. Diffusion's board of directors has delegated to the Compensation Committee the responsibility, among other things, to establish and lead a process for determining compensation payable to its non-employee directors. The Compensation Committee makes recommendations regarding compensation payable to Diffusion's non-employee directors to the entire board of directors, which then makes the final decision.

In making decisions regarding compensation to be paid to Diffusion's non-employee directors, Diffusion's board of directors considers factors such as its own views as to the form and amount of compensation to be paid, the current and anticipated time demands placed on non-employee directors and other factors that may be relevant, including the recommendations of Radford, when necessary and appropriate.

Diffusion and EIP believe that, after the completion of the Merger, the composition of the Compensation Committee will meet the requirements for independence under, and the Compensation Committee will comply with, any applicable requirements of the rules and regulations of Nasdaq and the SEC.

Processes and Procedures for Consideration and Determination of Director Compensation

The Compensation Committee of the combined company's board of directors is expected to retain the processes and procedures of the Compensation Committee of Diffusion's board of directors for consideration and determination of director compensation. Diffusion's board of directors has delegated to the Compensation Committee the responsibility, among other things, to establish and lead a process for determining compensation payable to its non-employee directors. The Compensation Committee makes recommendations regarding compensation payable to our non-employee directors to the entire board of directors, which then makes the final decision.

In making decisions regarding compensation to be paid to our non-employee directors, Diffusion's board of directors considers factors such as its own views as to the form and amount of compensation to be paid, the current and anticipated time demands placed on non-employee directors and other factors that may be relevant, including the recommendations of Radford, when necessary and appropriate.

Diffusion and EIP believe that, after the completion of the Merger, the composition of the Compensation Committee will meet the requirements for independence under, and the Compensation Committee will comply with, any applicable requirements of the rules and regulations of Nasdaq and the SEC.

Nominating and Corporate Governance Committee

Responsibilities

The Nominating and Corporate Governance Committee of the combined company will retain the responsibilities of the Nominating and Corporate Governance Committee of Diffusion's board of directors, which include:

- identifying individuals qualified to become members of the board of directors;
- recommending director nominees for each annual meeting of stockholders and director nominees to fill any vacancies that may occur between meetings of stockholders;
- general management and director succession planning;
- being aware of best practices in corporate governance, and developing and recommending to the board of directors a set of corporate governance standards to govern the board of directors, its committees, the company, and its employees in the conduct of our business and affairs;
- developing and overseeing a board of directors and committee evaluation process; and
- reviewing and discussing with the Chief Executive Officer and reporting periodically to the board of directors plans for executive officer development and succession plans for the Chief Executive Officer and other key executive officers and employees.

The Nominating and Corporate Governance Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition

In connection with the closing of the Merger, the combined company's board of directors is expected to select members of the Nominating and Corporate Governance Committee. Diffusion and EIP believe that, after the completion of the Merger, the composition of the Nominating and Corporate Governance Committee will meet the independence requirements under the Listing Rules of the Nasdaq Capital Market.

Processes and Procedures for Consideration of Director Nominations

The Nominating and Corporate Governance Committee of the combined company's board of directors is expected to retain the processes and procedures of the Nominating and Corporate Governance Committee of Diffusion's board of directors for consideration of director nominations. In selecting nominees for Diffusion's board of directors, the Nominating and Corporate Governance Committee first determines whether the incumbent directors are qualified to serve, and wish to continue to serve, on Diffusion's board of directors. The Nominating and Corporate Governance Committee believes that Diffusion and its stockholders benefit from the continued service of certain qualified incumbent directors because those directors have familiarity with and insight into Diffusion's affairs that they have accumulated during their tenure with Diffusion. Appropriate continuity of Diffusion board of directors' membership also contributes to Diffusion's board of directors' ability to work as a collective body. Accordingly, it is the practice of the Nominating and Corporate Governance Committee, in general, to re-nominate an incumbent director at the upcoming annual meeting of stockholders if the director wishes to continue his or her service with Diffusion's board of directors, the director continues to satisfy the Nominating and Corporate Governance Committee's criteria for membership on Diffusion's board of directors, the Nominating and Corporate Governance Committee believes the director continues to make important contributions to Diffusion's board of directors and there are no special, countervailing considerations against re-nomination of the director.

In identifying and evaluating new candidates for election to the board of directors, the Nominating and Corporate Governance Committee from time to time solicits recommendations from persons with whom the Nominating and Corporate Governance Committee is familiar and who are knowledgeable about the Company and the biotech industry generally for nominees likely to have the qualifications, skills and characteristics required for Board nominees. Such persons may include members of the board of directors and senior management of Diffusion. In addition, the Nominating and Corporate Governance Committee may engage a search firm to assist it in identifying qualified candidates. The Nominating and Corporate Governance Committee would typically review and evaluate each candidate whom it believes merits serious consideration, taking into account available information concerning the candidate, any qualifications or criteria for board membership established by the Nominating and Corporate Governance Committee, the existing composition of Diffusion's board of directors (including with respect to diversity), and other factors that it deems relevant. In conducting its review and evaluation, the Nominating and Corporate Governance Committee may solicit the views of management, other board members and any other individuals it believes may have insight into a candidate. The Nominating and Corporate Governance Committee may designate one or more of its members and/or other members of Diffusion's board of directors to interview any proposed candidate. The Nominating and Corporate Governance Committee also, in general, considers recommendations for the nomination of directors submitted by Diffusion stockholders in the same manner.

There are no formal requirements or minimum qualifications that a candidate must meet in order for the Nominating and Corporate Governance Committee to recommend the candidate to Diffusion's board of directors. The Nominating and Corporate Governance Committee believes that each nominee should be evaluated based on his or her merits as an individual, taking into account the needs of Diffusion and Diffusion's board of directors. However, in evaluating candidates, there are a number of criteria that the Nominating and Corporate Governance Committee generally views as relevant and is likely to consider. Some of these factors include:

- whether the candidate is an "independent director" under applicable independence tests under the federal securities laws and rules and regulations of the SEC;
- whether the candidate is "financially sophisticated" and otherwise meets the requirements for serving as a member of an audit committee;
- whether the candidate is an "audit committee financial expert" under the rules and regulations of the SEC for purposes of serving as a member of the Audit Committee;
- the needs of Diffusion with respect to the particular talents and experience of our directors;
- the personal and professional integrity and reputation of the candidate;
- the candidate's level of education and business experience;
- the candidate's business acumen;
- the candidate's level of understanding of Diffusion's business and industry and other industries relevant to its business;
- the candidate's ability and willingness to devote adequate time to the work of Diffusion's board of directors and its committees;
- the fit of the candidate's skills and personality with those of other directors and potential directors in building a board of directors that is effective, collegial and responsive to the needs of the company;

- whether the candidate possesses strategic thinking and a willingness to share ideas;
- the candidate's diversity of experiences, expertise and background, in general and as compared to other directors on Diffusion's board of directors; and
- the candidate's ability to represent the interests of all stockholders and not a particular interest group.

While Diffusion does not have a stand-alone diversity policy, in considering whether to recommend any director nominee, including candidates recommended by stockholders, the Nominating and Corporate Governance Committee will consider the factors described above. The Nominating and Corporate Governance Committee seeks nominees with a broad diversity of experience, expertise, and backgrounds. The Nominating and Corporate Governance Committee does not assign specific weights to particular criteria and no particular criterion is necessarily applicable to all prospective nominees. Diffusion and EIP believe that the backgrounds and qualifications of the directors, considered as a group, should provide a significant mix of experience, knowledge and abilities that will allow the combined company's board of directors to fulfill its responsibilities.

Diffusion and EIP believe that, after the completion of the Merger, the composition of the Nominating and Corporate Governance Committee will meet the requirements for independence under, and the Compensation Committee will comply with, any applicable requirements of the rules and regulations of Nasdaq and the SEC.

Code of Business Conduct and Ethics

The board of directors of the combined company will maintain a Code of Business Conduct and Ethics which applies to all of its directors, executive officers and other employees and meets the requirements of the SEC. A copy of the Code of Business Conduct and Ethics will be made available on the combined company's website.

DIFFUSION EXECUTIVE AND DIRECTOR COMPENSATION**Summary Compensation Table**

The table below provides summary compensation information concerning compensation awarded for service during the years ended December 31, 2022 and December 31, 2021 to the individuals that served as Diffusion's named executive officers during the year ended December 31, 2022 that are expected to continue as executive officers of the combined company. Diffusion refers to these two executives as Diffusion's continuing executive officers.

Name and Principal Position	Year	Salary (1)	Bonus Compensation (2)	Stock Awards	Option Awards (3)	All Other Compensation (4)	Total
Robert J. Cobuzzi, Jr., Ph.D. <i>Chief Executive Officer</i>	2022	\$ 450,000	\$ 202,500	\$ --	\$ --	\$ 39,287	\$ 691,787
	2021	\$ 410,000	\$ 164,000	\$ --	\$ 170,735	\$ 38,617	\$ 783,352
William R. Elder <i>General Counsel</i>	2022	\$ 292,782	\$ 115,283	\$ --	\$ --	\$ 5,858	\$ 413,923
	2021	\$ 256,250	\$ 76,234	\$ --	\$ 66,246	\$ 5,877	\$ 404,607

(1) Represents cash portion of base salary.

(2) Represents the annual cash incentive bonuses for service during the applicable year by Diffusion's continuing executive officers.

(3) The amounts shown in this column reflect the grant date fair value of option awards granted for service during the applicable year, calculated in accordance with the provisions of ASC Topic 718 and determined without regard to forfeitures. Amounts shown for 2021 include the full grant date fair value of (i) time-based awards granted in January 2022 and (ii) milestone-based, performance awards granted in March 2021. Pursuant to the terms of the award agreements for the performance awards, two-thirds of the underlying shares originally granted were automatically forfeited due to the first patient in the ILD-DLCO Trial not being dosed on or before September 30, 2021. Diffusion subsequently announced dosing of the first patients in the ILD-DLCO Trial on December 16, 2021.

(4) The amounts reported in this column for 2021 represent (w) with respect to Dr. Cobuzzi, (i) \$11,600 in 401(k) Plan matching contributions by the Company and (iii) \$27,017 in Company-paid health insurance premiums, and (x) with respect to Mr. Elder, \$5,877 in Company-paid health insurance premiums. The amounts reported in this column for 2022 represent (w) with respect to Dr. Cobuzzi, (i) \$11,600 in 401(k) Plan matching contributions by the Company and (ii) \$39,287 in Company-paid health insurance premiums, and (x) with respect to Mr. Elder, \$5,858 in Company-paid health insurance premiums.

Employment Agreements*Robert J. Cobuzzi, Jr., Ph.D., President & Chief Executive Officer of Diffusion*

Effective September 8, 2020, Diffusion entered into an employment agreement with Dr. Cobuzzi pursuant to which he serves as its President & Chief Executive Officer. The employment agreement has an indefinite term. Dr. Cobuzzi is currently entitled to an initial annual base salary of \$410,000, subject to an increase at the discretion of Diffusion's board of directors. Dr. Cobuzzi has the opportunity to earn a target annual bonus of 50 percent of his base salary. For 2022, Dr. Cobuzzi's entire base salary was paid in cash. The employment agreement contains certain severance and change of control provisions as described in more detail under the heading "*—Post-Termination Severance and Change in Control Arrangements*" below. The employment agreement also contains certain non-competition and non-solicitation provisions (each applicable during employment and for 24 months thereafter), as well as confidentiality and non-disparagement provisions (each applicable during employment and at all times thereafter). On March 29, 2023, Diffusion entered into an amendment to its employment agreement with Dr. Cobuzzi, pursuant to which certain provisions in the original employment agreement which permitted Diffusion to pay a portion of his base salary and/or annual cash bonus in the form of equity or equity-based compensation, as determined in the good faith discretion of Diffusion's board of directors, were eliminated.

William R. Elder, General Counsel & Corporate Secretary of Diffusion

Effective September 23, 2020, Diffusion entered into an employment agreement with Mr. Elder pursuant to which he serves as its General Counsel & Corporate Secretary. The employment agreement has an indefinite term. Mr. Elder is entitled to an initial annual base salary of \$250,000, subject to an increase at the discretion of the Board. Mr. Elder has the opportunity to earn a target annual bonus of 30 percent of his base salary. For 2022, Mr. Elder's entire pro-rated base salary was paid in cash. The employment agreement contains certain severance and change of control provisions as described in more detail below under the heading "*—Post-Termination Severance and Change in Control Arrangements*" below. The employment agreement also contains certain non-competition and non-solicitation provisions (each applicable during employment and for 24 months thereafter), as well as confidentiality and non-disparagement provisions (each applicable during employment and at all times thereafter). On March 29, 2023, Diffusion entered into an amendment to its employment agreement with Mr. Elder, pursuant to which certain provisions in the original employment agreement which permitted Diffusion to pay a portion of his base salary and/or annual cash bonus in the form of equity or equity-based compensation, as determined in the good faith discretion of Diffusion's board of directors, were eliminated.

Long-Term Equity Incentive Compensation and Other Compensatory Arrangements

Diffusion's board of directors administers Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended (the "2015 Equity Plan"), in which Diffusion's continuing executive officers participate, the bonus payments made to Diffusion's continuing executive officers provided for in the employment agreements described below under the heading "*—Employment Agreements,*" and any other compensation-related matters as they otherwise determine in their discretion.

In the first quarter of 2021, the Compensation Committee of Diffusion's board of directors granted 50% of the annual long-term equity incentive awards granted to Diffusion's continuing executive officers at the outset of the year in the form of performance-based options the vesting of which was dependent on the achievement of specified performance metrics during calendar year 2021. The remaining 50 percent were granted in the form of option awards subject to time-based vesting in accordance with Diffusion's past practice.

In the first quarter of 2022, the Compensation Committee of Diffusion's board of directors returned to Diffusion's historic practice of granting all such awards as options subject to time-based vesting.

In consideration of, among other things, uncertainties regarding Diffusion's long-term focus pending the completion of Diffusion's board of director's strategic review process, the Compensation Committee of Diffusion's board of directors made the determination that no equity-based compensation would be awarded to Diffusion's continuing executive officers or other named executive officers or employees in the first quarter of 2023 (other than the continued vesting of previously granted awards).

2022 Bonus Compensation

Executive bonuses are determined by the Compensation Committee of Diffusion's board of directors. The Compensation Committee of Diffusion's board of directors determines whether bonuses are earned and the amounts of the bonus payout by considering a number of factors, the principal factor being based upon the performance goals developed by the Compensation Committee of Diffusion's board of directors. Other important factors include clinical trial progress, business development activities, status of public filings, capital raising transactions, and stock price performance.

Outstanding Equity Awards at Fiscal Year End

Option Awards

The table below provides information regarding unexercised stock option awards held by each of Diffusion’s continuing executive officers that remained outstanding as of December 31, 2022. Unless otherwise indicated, each grant was awarded under our 2015 Equity Plan.

Name	Award Type	Grant Date	Shares Underlying Unexercised Options Exercisable	Shares Underlying Unexercised Options Unexercisable	Exercise Price	Expiration Date
Robert J. Cobuzzi, Jr., Ph.D.	NQO	1/7/2020	2,372	—	\$ 25.50	1/7/2030
	NQO	6/17/2020	1,226	—	\$ 50.00	6/17/2030
	NQO	9/8/2020	7,128	2,372	\$ 39.50	9/8/2030
	NQO	3/1/2021	660	414	\$ 55.50	3/1/2031
	NQO**	3/1/2021	719	355	\$ 55.50	3/1/2031
	NQO	1/27/2022	5,100	10,187	\$ 12.00	1/7/2023
William R. Elder	NQO*	9/22/2020	1,053	347	\$ 41.00	9/22/2030
	NQO	3/1/2021	1,078	675	\$ 55.50	3/1/2031
	NQO**	3/1/2021	283	133	\$ 55.50	3/1/2031
	NQO	1/27/2022	2,040	4,074	\$ 12.00	1/27/2023

* Non-plan-based equity award grant made as an inducement to the individual’s acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

** Pursuant to the terms of the corresponding award agreements, two-thirds of the underlying shares originally granted were automatically forfeited on October 1, 2021 due to non-achievement of certain specified performance metrics.

Restricted Stock Unit Awards

The table below provides information regarding restricted stock unit awards held by each of Diffusion’s continuing executive officers that remained outstanding as of December 31, 2022, if any. Each grant was awarded under the 2015 Equity Plan.

Name	Award Type	Grant Date	Number of Shares That Have Not Vested	Market Value of Shares That Have Not Vested*
Robert J. Cobuzzi, Jr., Ph.D.	RSU	1/7/2020	327	\$ 1,655

* Based on a price per share of \$5.06, the closing price of Diffusion Common Stock on December 30, 2022, as reported by Nasdaq. The award was granted to Dr. Cobuzzi in connection with his appointment as a non-employee director in January 2020 and vested in six tri-monthly installments. The first such installment vested on October 31, 2021 and the final installment vested on January 31, 2023.

401(k) Retirement Plan

Diffusion maintains its 401(k) Plan pursuant to which all eligible employees are entitled to make pre-tax and after-tax contributions of their compensation. In addition, Diffusion makes discretionary matching contributions at a rate of 100% for contributions up to 3% of the participant’s eligible compensation and 50% for any additional contributions up to 5% of the participant’s eligible compensation. The matching contributions received by Diffusion’s named executive officers in 2022 and 2021 are reported in the “All Other Compensation” column of the Summary Compensation Table above.

Post-Termination Severance and Change in Control Arrangements

As described under the heading “—Employment Agreements,” Diffusion has entered into employment agreements, as amended, with each of Dr. Cobuzzi and Mr. Elder that provide for certain severance and change of control benefits, subject to the execution and non-revocation of a release of claims by the executive or his estate (as applicable).

Under Dr. Cobuzzi’s employment agreement, if his employment is terminated by Diffusion other than for “cause,” death or “disability,” or by Dr. Cobuzzi for “good reason” (as such terms are defined in the employment agreement), Dr. Cobuzzi will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, continuation of base salary for 12 months, plus 12 months of COBRA premium reimbursement, provided that if such termination occurs within 60 days before or within 24 months following a “change of control” (as defined in the employment agreement), then Dr. Cobuzzi will be entitled to receive the same severance benefits as described above, except that he will receive (a) a payment equal to two times the sum of his base salary and the higher of his target annual bonus opportunity and the bonus payment he received for the year immediately preceding the year in which the termination occurred instead of 12 months of base salary continuation, and (b) a payment equal to 36 times the monthly COBRA premium for him and his eligible dependents instead of 12 months of COBRA reimbursements (the payments in clauses (a) and (b) are paid in a lump sum in some cases and partly in a lump sum and partly in installments over 12 months in other cases). In addition, if Dr. Cobuzzi’s employment is terminated by us without cause or by Dr. Cobuzzi for good reason, in either case, upon or within 24 months following a change of control, then Dr. Cobuzzi will be entitled to full vesting of all equity awards received by him from us (with any equity awards that are subject to the satisfaction of performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 24 months following the termination date (but in no event beyond the expiration date of the applicable option or stock appreciation right)).

Under the employment agreement for Mr. Elder, in the event that his employment is terminated by Diffusion other than for “cause”, death or “disability,” or upon Mr. Elder’s resignation for “good reason” (as such terms are defined in the applicable employment agreement), he will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, continuation of base salary for nine months, plus 12 months of COBRA premium reimbursement, provided that if such termination occurs within 60 days before or within 24 months following a “change of control” (as defined in the employment agreement), then he will be entitled to receive the same severance benefits as described above, except that the executive will receive (a) a payment equal to 1.5 times the sum of his base salary and the higher of the executive’s target annual bonus opportunity and the bonus payment he received for the year immediately preceding the year in which the termination occurred instead of nine months of base salary continuation and (b) a payment equal to 18 times the monthly COBRA premium for Mr. Elder and any eligible dependents instead of 12 months of COBRA reimbursements (the payments in clauses (a) and (b) are paid in a lump sum in some cases and in installments over nine or 12 months in other cases). In addition, if Mr. Elder’s employment is terminated by Diffusion without cause or by Mr. Elder for good reason, in either case, upon or within 24 months following a change of control, then Mr. Elder will be entitled to full vesting of all equity awards received by the executive from us (with any equity awards that are subject to the satisfaction of performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 24 months following the termination date (but in no event beyond the expiration date of the applicable option or stock appreciation right)).

Under the employment agreements for each of Diffusion’s continuing executive officers, in the event that the executive’s employment is terminated due to his death or disability, the executive (or the executive’s estate) will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, 12 months of COBRA premium reimbursement and accelerated vesting of (a) all equity awards received in payment of base salary or an annual bonus and (b) with respect to any other equity award, the greater of the portion of the unvested equity award that would have become vested within 12 months after the termination date had no termination occurred and the portion of the unvested equity award that is subject to accelerated vesting (if any) upon such termination under the applicable equity plan or award agreement (with performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 12 months following the termination date or, if longer, such period as provided under the applicable equity plan or award agreement (but in no event beyond the expiration date of the applicable option or stock appreciation right)).

Further, under the terms of the stock option agreements with Diffusion’s continuing executive officers, upon a completion of a “change of control” (as defined in the 2015 Equity Plan), options held by Diffusion’s continuing executive officers will become immediately vested and remain exercisable through their expiration date regardless of whether the holder remains in the employment or service of the Company after the change of control. Alternatively, in connection with a change of control, the Compensation Committee of Diffusion’s board of directors may, in its sole discretion, cash out the options.

Director Compensation Table for 2022

The table below provides summary information concerning the compensation of each individual who served as a non-employee director of Diffusion during the year ended December 31, 2022 who is expected to serve as a director of the combined company:

	Fees Earned or Paid in Cash	Stock Awards	Option Awards	All Other Compensation	Total
Robert J. Cobuzzi, Jr., Ph.D. (1)	\$ -	\$ -	\$ -	\$ 691,787	\$ 691,787
Jane H. Hollingsworth	\$ 77,500	\$ -	\$ -	\$ -	\$ 77,500

(1) Reflects compensation for Dr. Cobuzzi’s service as Diffusion’s President and Chief Executive Officer. See “*Diffusion Executive Compensation – Summary Compensation Table*” for additional information. Dr. Cobuzzi did not receive any additional compensation for his service as a director.

Combined Company Non-Employee Director Compensation Policy

The combined company expects to adopt a non-employee director compensation policy, pursuant to which non-employee directors will be eligible to receive compensation for service on the combined company’s board of directors and committees of the board of directors.

EIP EXECUTIVE AND DIRECTOR COMPENSATION

This section describes the material elements of compensation awarded to, earned by or paid to each of EIP’s named executive officers in 2022 and 2021. EIP’s named executive officers for 2022 were John Alam, M.D., Sylvie Grégoire, Pharm.D., and Kelly Blackburn. This section also provides qualitative information regarding the manner and context in which compensation is awarded to and earned by EIP’s named executive officers and is intended to place in perspective the data presented in the tables and narrative that follow.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to EIP’s named executive officers during 2022 and 2021.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Option Awards (\$)(2)	All Other Compensation (\$)	Total (\$)
John Alam, M.D. (3) <i>President and Chief Executive Officer</i>	2022	\$ 449,904	\$ 143,969	—	\$ --	\$ 593,873
	2021	\$ 446,299	\$ 71,985(5)	—	\$ --	\$ 518,284(6)
Sylvie Grégoire, Pharm.D. (4) <i>Executive Chair of the Board of Directors</i>	2022	\$ 347,068	\$ 111,062	—	\$ --	\$ 458,130
	2021	\$ 344,287	\$ 55,531(5)	—	\$ --	\$ 399,818(7)
Kelly Blackburn <i>SVP, Clinical Development</i>	2022	\$ 263,194	\$ 63,552	—	\$ --	\$ 326,746
	2021	\$ 255,028	\$ 30,851	\$ 167,227	\$ --	\$ 453,106

- (1) The amounts reported in the “Bonus” column for 2022 represent discretionary annual cash bonuses awarded to EIP’s named executive officers for service during 12-month period from January 1, 2022 to December 31, 2022, which were paid in 2023. Amounts for 2021 represent cash bonuses earned for the 12-month period from January 1, 2021 to December 31, 2021, which were paid in 2022.
- (2) The amounts reported in the “Options Awards” column reflect the aggregate grant date fair value of share-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification (“ASC”) Topic 718. See Note 2 to EIP’s financial statements appearing elsewhere in this proxy statement/prospectus/information statement regarding assumptions underlying the valuation of equity awards.
- (3) Dr. Alam also serves as a member of EIP’s board of directors but does not receive any compensation for his service as a director.
- (4) Dr. Grégoire also serves as a member of our board of directors but does not receive any compensation for her service as a director.
- (5) In 2021, to provide additional cash resource to the company, Dr. Alam and Dr. Grégoire offered to forego, without repayment, their bonuses, i.e., they each received \$0 in bonus in 2021. Instead, the amounts of their bonus were recorded as contributed capital in lieu of salary in additional paid-in capital, will not be paid in cash, debt or equity in the future.
- (6) The paid out total, with forgoing the bonus, was \$446,299.
- (7) The paid out total, with forgoing the bonus, was \$344,287.

Narrative to Summary Compensation Table

EIP uses base salaries to recognize the experience, skills, knowledge and responsibilities required of all of its employees, including its named executive officers. None of EIP's named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary. Pursuant to the terms of EIP's employment agreements and/or offer letters with its named executive officers, in 2022, EIP paid base salaries in the amounts of \$449,904, \$347,068, and \$263,194 to Dr. Alam, Dr. Grégoire, and Ms. Blackburn, respectively.

Pursuant to the terms of their employment agreements, Dr. Alam, Dr. Grégoire, and Ms. Blackburn are eligible to receive an annual cash bonus with a target amount of such bonus equal to 40%, 40% and 30%, respectively, of the applicable executive's base salary. EIP's board may determine to award more or less than the target bonus amount. In 2021, EIP's board of directors awarded a cash bonus to Ms. Blackburn in the amount of \$30,851, which was paid in 2022.

EIP believes that equity grants provide its named executive officers with a strong link to its long-term performance, create an ownership culture and help to align the interests of its named executive officers and its stockholders. In addition, EIP believes that equity grants with a time-based vesting feature promote executive retention because this feature incents EIP's named executive officers to remain in EIP's employment during the vesting period. Accordingly, EIP's board of directors periodically reviews the equity incentive compensation of its named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

Outstanding Equity Awards at Year End

The following table sets forth information regarding outstanding equity awards held by EIP's named executive officers as of December 31, 2022:

Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$/share)	Option Expiration Date
John Alam, M.D.	—	—	—	—
Sylvie Grégoire, Pharm.D.	—	—	—	—
Kelly Blackburn	72,000 ⁽¹⁾	—	\$ 2.28	5/29/2028
	47,000 ⁽²⁾	1,000	\$ 3.19	3/4/2029
	30,000 ⁽³⁾	10,000	\$ 3.00	12/16/2029
	26,250 ⁽⁴⁾	33,750	\$ 4.01	3/12/2031

- (1) These options were granted on May 29, 2018 and vest, subject to Ms. Blackburn's continued service at EIP, as follows: 25% of the shares vested on May 1, 2019, with the remainder vesting over the next three years in equal monthly installments thereafter.
- (2) These options were granted on March 4, 2019 and vest, subject to Ms. Blackburn's continued service at EIP, as follows: 25% of the shares vested on January 29, 2020, with the remainder vesting over the next three years in equal monthly installments thereafter.
- (3) These options were granted on December 16, 2019 and vest, subject to Ms. Blackburn's continued service at EIP, as follows: 25% of the shares vested on December 16, 2020, with the remainder vesting over the next three years in equal monthly installments thereafter.

- (4) These options were granted on March 12, 2021 and vest, subject to Ms. Blackburn's continued service at EIP, as follows: 25% of the shares vested on March 12, 2022, with the remainder vesting over the next three years in equal monthly installments thereafter.

EIP's Agreements with its Named Executive Officers

Employment Agreements, Severance and Change in Control Agreements

John Alam, M.D.

In April 2018, EIP entered into an employment agreement with John Alam, M.D. pursuant to which Dr. Alam serves as EIP's President and Chief Executive Officer. Dr. Alam's employment agreement establishes his title, his base salary, his eligibility for an annual bonus of up to 40% of his base salary, and his eligibility for benefits made available to employees generally. Dr. Alam's employment is at will.

Pursuant to the employment agreement, the term of Dr. Alam's employment commenced on April 2, 2018 and continues until immediately prior to the consummation of a qualified financing, unless earlier terminated (a) immediately upon the executive's death, (b) by EIP upon executive's disability or for cause, as such terms are defined in the employment agreement, in each case upon notice thereof, or by EIP for reasons other than for disability for cause, upon at least 30 days prior notice, or (c) by the executive, upon at least 30 days prior notice. The employment agreement specifies that a qualified financing occurs when EIP sells shares of its preferred stock with (i) an aggregate purchase price of not less than \$20.0 million, (ii) a price per share equal to at least one and one-half times the Series B original issue price, as defined in our certificate of incorporation, and (iii) the principal purpose of raising capital.

Sylvie Grégoire, Pharm.D.

In April 2018, EIP entered into an employment agreement with Sylvie Grégoire, Pharm.D. pursuant to which Dr. Grégoire serves as EIP's Executive Chair of the Board of Directors. Dr. Grégoire's employment agreement establishes her title, her base salary of \$180,000, and her eligibility for benefits made available to employees generally. Dr. Grégoire's employment is at will. The terms of her employment agreement specify that Dr. Grégoire will devote 1/3 of her business time and energies to the business affairs of EIP. In March 2019, EIP and Dr. Grégoire entered into an amendment to the employment agreement pursuant to which (a) the percentage of Dr. Grégoire's business time and energies to be devoted to EIP was increased to 60%, (b) Dr. Grégoire's annual base salary was increased to \$333,720, and (c) Dr. Grégoire is eligible to receive an annual bonus of up to 40% of her base salary.

Pursuant to the employment agreement, the term of Dr. Grégoire's employment commenced on April 2, 2018 and continues until immediately prior to the consummation of a qualified financing, unless earlier terminated (a) immediately upon the executive's death, (b) by EIP upon executive's disability or for cause, as such terms are defined in the employment agreement, in each case upon notice thereof, or by EIP for reasons other than for disability for cause, upon at least 30 days prior notice, or (c) by the executive, upon at least 30 days prior notice. The employment agreement specifies that a qualified financing occurs when EIP sells shares of its preferred stock with (i) an aggregate purchase price of not less than \$20.0 million, (ii) a price per share equal to at least one and one-half times the Series B original issue price, as defined in EIP's certificate of incorporation, and (iii) the principal purpose of raising capital.

Kelly Blackburn

In April 2018, EIP entered into an offer letter of employment with Kelly Blackburn, pursuant to which Ms. Blackburn serves as EIP's Vice President Clinical Development. Ms. Blackburn's employment offer letter establishes her title, her base salary of \$180,000, and her eligibility for benefits made available to employees generally. Ms. Blackburn's employment is at will. The terms of her employment agreement specify that Ms. Blackburn will devote approximately 60% of her business time and energies to the business affairs of EIP. In connection with her employment, in May 2018, Ms. Blackburn was granted a non-qualified stock option to purchase 72,000 shares of EIP Common Stock at a price per share of \$2.28, which was the fair market value on the date of the grant. The option vested as to 25% of the shares on May 1, 2019 with the remainder vesting over the subsequent three years in equal monthly installments. In January 2019, EIP and Ms. Blackburn entered into an amendment to her employment offer letter, pursuant to which (a) the percentage of Ms. Blackburn's business time and energies to be devoted to EIP was increased to 80% and (b) Ms. Blackburn's annual base salary was increased to \$240,000. Ms. Blackburn continues to be eligible to receive an annual bonus of up to 30% of her base salary. In connection with entry into the amendment to her offer letter, Ms. Blackburn was granted in March 2019 a non-qualified stock option to purchase 48,000 shares of EIP Common Stock at a price per share of \$3.19, which was the fair market value on the date of the grant. The option vested as to 25% of the shares on January 29, 2020, with the remainder vesting over the subsequent three years in equal monthly installments.

Other Agreements

EIP has also entered into employee confidentiality, inventions, non-solicitation and non-competition agreements with Dr. Alam and Dr. Grégoire. Under the employee confidentiality, inventions, non-solicitation and non-competition agreements, each of Dr. Alam and Dr. Grégoire has agreed (1) not to compete with EIP during his or her employment and for a period of one year after the termination of his or her employment, (2) not to solicit EIP's employees during his or her employment and for a period of two years after the termination of his or her employment, (3) to protect EIP's confidential and proprietary information and (4) to assign to EIP related intellectual property developed during the course of his or her employment.

Stock Option and Other Compensation Plans

Prior to the Merger, EIP granted awards to eligible participants under the EIP Plan. At the Effective Time, each share of EIP capital stock outstanding will be converted into the right to receive a number of shares of Diffusion Common Stock calculated using the Exchange Ratio. Diffusion will assume outstanding and unexercised options to purchase shares of EIP capital stock, and in connection with the Merger such options will be converted into options to purchase shares of Diffusion Common Stock, with the number of Diffusion shares subject to such option and the exercise price being appropriately adjusted to reflect the Exchange Ratio.

2018 Employee, Director and Consultant Equity Incentive Plan

The EIP Plan was first adopted by EIP's board of directors and first approved by EIP stockholders in March 2018. Under the EIP Plan, EIP's board of directors may issue incentive stock options, non-qualified stock options, stock grants, and other stock-based awards to employees, directors, and consultants, as specified in the EIP Plan. EIP's employees, officers, directors, consultants and advisors are eligible to receive awards under the EIP Plan; however, incentive stock options may only be granted to employees. In accordance with the terms of the EIP Plan, EIP's board of directors, or a committee appointed thereby, administers the EIP Plan and, subject to any limitations in the EIP Plan, selects the recipients of awards and determines:

- the number of shares of common stock covered by options and the dates upon which those options become exercisable;
- the type of options to be granted;
- the exercise prices of options;
- the duration of options; and
- the number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of those awards, including the issue price, conditions for repurchase or forfeiture and repurchase price.

If EIP's board of directors delegates authority to an executive officer to grant awards under the EIP Plan, the executive officer has the power to make awards to employees, directors, consultants and advisors, except officers or executive officers. EIP's board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards, and the maximum number of shares subject to awards that such executive officer may make.

In the event of a corporate transaction, as defined in the EIP Plan, EIP's board of directors shall take any one or more of the following actions as to all or any outstanding awards on such terms as the board determines:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or succeeding corporation or an affiliate thereof;
- upon written notice to a participant, provide that all of the participant's unexercised awards shall become exercisable in full and will terminate immediately prior to the consummation of such corporate transaction, unless exercised by the participant within a specified period following the date of such notice;
- provide that all outstanding awards shall become realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such corporate transaction;
- in the event of a corporate transaction pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the corporate transaction, which we refer to as the acquisition price, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (a) the acquisition price times the number of shares of our common stock subject to the participant's awards to the extent the exercise price of such awards does not exceed the acquisition price minus (b) the aggregate exercise price of all such outstanding awards, in exchange for the termination of such options or other awards;
- provide for any combination of the foregoing.
- As of December 31, 2022, there were options to purchase an aggregate of 995,000 shares of EIP Common Stock outstanding under the EIP Plan at a weighted average exercise price of \$2.87 per share, and no shares of common stock had been issued upon the exercise of options granted under the EIP Plan. As of December 31, 2022, there were 440,000 additional shares of EIP Common Stock available for future issuance under the EIP Plan.

401(k) Retirement Plan

EIP maintains a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of EIP's employees are eligible to participate, beginning on the first day of the month following commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit and have the amount of the reduction contributed to the 401(k) plan. Currently, we do not match employee contributions.

Compensation Changes in Connection with Merger

In connection with the Merger, EIP may enter into new or additional compensation arrangements with the named executive officers of the combined company. The terms of any such arrangements are not yet known.

Limitations on Liability and Indemnification

As permitted by Delaware law, the certificate of incorporation of Diffusion, as amended, which will become effective as of the Effective Time, will limit or eliminate the personal liability of the directors of the combined company, limit the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the General Corporation Law of the State of Delaware and provide that no director will have personal liability to the company or to its stockholders for monetary damages for breach of fiduciary duty. However, these provisions will not eliminate or limit the liability of any director:

- for any breach of the director's duty of loyalty to the combined company or its stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of the combined company's directors will be further limited to the greatest extent permitted by the General Corporation Law of the State of Delaware.

In addition, the certificate of incorporation of Diffusion, as amended and which will become effective at the Effective Time, will provide that the combined company must indemnify its directors and officers and must advance expenses, including attorneys' fees, to its directors and officers in connection with legal proceedings, subject to very limited exceptions.

EIP maintains a general liability insurance policy that covers specified liabilities of its directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, the combined company expects to enter into indemnification agreements with each of its directors and officers. These agreements will provide for the indemnification of such persons for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were officers, directors or agents of the combined company, or by reason of anything done or not done in their capacities as such.

Some of EIP's non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of EIP's board of directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling EIP, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

The combined company's directors and executive officers may, after the Effective Time, adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of the combined company's common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. The director or officer may amend or terminate the plan in some circumstances. The directors and executive officers of the combined company may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Director Compensation

The following table sets forth information regarding compensation earned by EIP's non-employee directors during 2022.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) ⁽¹⁾	Total (\$)
Marwan Sabbagh, M.D.	\$ 40,000	—	\$ 40,000
Jeff Poulton	\$ --	\$ 31,056	\$ 31,056
Frank Zavrl	\$ --	\$ 31,056	\$ 31,056

(1) The amounts reported in the "Options Awards" column reflect the aggregate grant date fair value of share-based compensation awarded during the year computed in accordance with the provisions of ASC Topic 718. See Note 2 to our financial statements appearing elsewhere in this proxy statement/prospectus/information statement regarding assumptions underlying the valuation of equity awards. As of December 31, 2022, the aggregate number of shares of our common stock subject to each non-employee director's outstanding option awards was as follows: Mr. Sabbagh, 40,000 shares; Mr. Poulton, 130,000 shares; and Mr. Zavrl, 130,000 shares.

In March 2018, EIP's board of directors approved compensation guidelines pursuant to which non-employee directors are paid \$10,000 per quarter. Such amounts earned in 2022 are reflected in the table above. In 2022, EIP granted options to purchase 20,000 shares of EIP Common Stock to each of Mr. Poulton and Mr. Zavrl, with an exercise price of \$2.24 per share. These options vest as to 25% on the first anniversary of the date of the grant, with the remainder to vest in equal monthly installments over 36 months.

EIP reimburses its non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of directors and committee meetings. The compensation that EIP pays to its President and Chief Executive Officer and Executive Chair is discussed earlier in this "EIP Executive and Director Compensation" section.

The combined company expects to adopt a non-employee director compensation policy, pursuant to which non-employee directors will be eligible to receive compensation for service on the combined company's board of directors and committees of the board of directors.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2021 and all currently proposed transactions, to which either Diffusion or EIP has been a participant, in which:

- the amounts exceeded or will exceed the lesser of \$120,000 or 1% of the average of the total assets of Diffusion or EIP, as the case may be, at year-end for the last two completed fiscal years; and
- any of the directors, executive officers or holders of more than 5% of the respective capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Diffusion

Diffusion's former Senior Director of Information Technologies, who is the son of the former Chairman of Diffusion's board of directors/Chief Executive Officer of Diffusion, received total compensation for 2022 and 2021 of approximately \$196,606 and \$151,250, respectively.

No family relationships exist among any of Diffusion's directors or executive officers.

Indemnification Agreements

The Diffusion certificate of incorporation that will become effective as of the Effective Time provides that the combined company will indemnify its directors and officers to the fullest extent permitted by Delaware law. In addition, the combined company will enter into indemnification agreements, with each of Diffusion's officers and directors who will serve as officers and directors of the combined company, that may be broader in scope than the specific indemnification provisions contained in the Delaware General Corporation Law.

Diffusion Related-Party Transactions Policy

Diffusion's Audit Committee is charged with the responsibility of reviewing and approving or ratifying all related person transactions in accordance with the Listing Rules of the Nasdaq Capital Market and other applicable law, rules and regulations and any related policies and procedures adopted by or on behalf of Diffusion and then in effect.

EIP

Convertible Notes

In December 2020, the Company issued 2020 Notes, to predominantly related party investors, for aggregate proceeds of \$5,078,500. In December 2021, the Company issued the 2021 Notes, to predominantly related party investors, for aggregate proceeds of \$6,000,000.

John Alam, M.D., EIP's President and Chief Executive Officer, purchased \$500,000 of the 2020 Notes; Sylvie Grégoire, Executive Chair of EIP, purchased \$500,000 of the 2020 Notes; Frank Zavrl, together with his spouse, Paula Zavrl, purchased an aggregate of \$350,000 of the 2020 Notes and \$1,000,000 of the 2021 Notes; Kelly Blackburn, EIP's Senior Vice President, Clinical Development, purchased an aggregate of \$150,000 of the 2020 Notes; and Jeff Poulton, a director of EIP, purchased \$100,000 of the 2020 Notes.

In April 2022, the Company entered into an amendment with the noteholders for the 2020 Notes (the "Amendment"). In accordance with the Amendment, the maturity of the 2020 Notes was extended from June 2022 to December 2023, the interest rate was modified so interest accrued at 5% through the original maturity of June 2022 and at 0% thereafter, the conversion discount was increased from 20% to 30%, and a conversion price limit of \$3.00 was established for certain conversion scenarios. The 2021 Notes do not accrue any interest and have a maturity date of December 2023. No payments of principal or interest are due prior to maturity.

Subsequent to the Amendment, the terms of the 2020 Notes and the 2021 Notes provide for automatic conversion upon either (i) the occurrence of a qualified financing of at least \$15,000,000 in gross proceeds, in which the outstanding principal and all accrued and unpaid interest shall convert into shares of the equity financing at a conversion price equal to the lesser of 70% of the price per share or \$3.00 per share; (ii) the occurrence of an initial public offering, in which the outstanding principal and all accrued and unpaid interest shall convert into common shares offered in the initial public offering at a conversion price equal to the initial public offering price; or (iii) the occurrence of special purpose acquisition company ("SPAC") transaction or a Reverse Merger, in which the outstanding principal and all accrued and unpaid interest shall convert into common shares determined in connection with and at the time of the SPAC transaction, or Reverse Merger, at the conversion price. The terms of the 2020 Notes and the 2021 Notes further provide the holders an option to convert in connection with a financing transaction that is not a qualified financing in which the outstanding principal and all accrued and unpaid interest shall convert into shares of the equity financing at a conversion price equal to the lesser of 70% of the price per share or \$3.00 per share for the 2020 Notes and the 2021 Notes.

The terms of the 2020 Notes and the 2021 Notes further provide for payment of 150% of all outstanding principal and all accrued and unpaid interest in the event of a change in control of the Company. The 2021 Notes also have the option to fully convert to common stock at a price per share equal to the conversion price in the event of a change in control.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On March 30, 2023, Diffusion, Merger Sub, and EIP entered into the Merger Agreement, pursuant to which, among other things, and subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will merge with and into EIP at the Effective Time, with EIP continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Diffusion. In connection with the Merger, Diffusion intends to change its corporate name from “Diffusion Pharmaceuticals Inc.” to “CervoMed Inc.”

At the Effective Time, each outstanding share of EIP Common Stock (other than certain excluded shares and dissenting shares, but after giving effect to the conversion of the EIP Convertible Notes and EIP Preferred Stock) will be converted into the right to receive a number of shares of Diffusion Common Stock based upon the Exchange Ratio calculated as set forth in the Merger Agreement. Each excluded share will automatically be cancelled and will cease to exist, and no consideration will be delivered in exchange therefor. In addition, (i) each EIP Option granted under the EIP Plan, whether vested or unvested, that is outstanding immediately prior to the Effective Time will be assumed by Diffusion and converted into an option to purchase shares of Diffusion Common Stock, on the same terms and conditions as were applicable to such EIP Option immediately prior to the Effective Time and (ii) each EIP warrant that is outstanding and unexercised immediately prior to the Effective Time will be assumed by Diffusion and converted into and become a warrant to purchase Diffusion Common Stock, in each case, with the number of underlying shares and exercise price adjusted to give effect to the Exchange Ratio.

Immediately following the Effective Time, former EIP stockholders are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and stockholders of Diffusion as of immediately prior to the Effective Time are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, in each case, assuming Diffusion’s net cash at the closing of the Merger is between \$13.5 million and \$14.5 million. Under certain circumstances further described in the Merger Agreement and elsewhere in this prospectus/proxy statement/information statement, these ownership percentages may be adjusted upward or downward if the amount of Diffusion’s net cash at the closing of the Merger is above \$14.5 million or below \$13.5 million.

At the special meeting, Diffusion has recommended that stockholders approve the Reverse Split Proposal. If approved by stockholders and implemented by the Diffusion board of directors, which may be necessary to satisfy certain listing requirements of Nasdaq the satisfaction of which is a condition to closing the Merger, upon the effectiveness of the Reverse Split, the outstanding shares of Diffusion Common Stock immediately prior to the Reverse Split will be combined into a lesser number of shares based upon a factor within the approved range to be determined by Diffusion’s board of directors prior to the effective time of the Reverse Split. As the Reverse Split may not be required to consummate the Merger and, if required, will be effected at an exact ratio that has not been determined and would be subject to a variety of factors, including the closing price of the Diffusion Common Stock, these unaudited pro forma condensed combined financial statements do not reflect any adjustments related to the Reverse Split.

Accordingly, the following selected unaudited pro forma condensed combined financial information gives effect to the (i) the conversion of the EIP Convertible Notes into EIP Common Stock immediately prior to the Effective Time of the Merger, (ii) the conversion of the EIP Preferred Stock into EIP Common Stock immediately prior to the Effective Time of the Merger, and (iii) the Merger.

The Merger has been accounted for as a reverse recapitalization of Diffusion by EIP under GAAP for purposes of these unaudited pro forma condensed combined financial information, similar to the issuance of equity for the net assets of Diffusion, which as of the Effective Time are assumed to be primarily cash, cash equivalents and marketable securities. EIP has been determined to be the acquiring company in the Merger for financial reporting purposes based upon several factors, including: (i) former EIP securityholders are expected to own approximately 77.3% of the Diffusion Common Stock outstanding immediately following the Effective Time (subject to adjustment in accordance with the Merger Agreement), (ii) EIP is entitled to designate the majority (five of seven) of initial members of the board of directors of the combined company, and (iii) EIP’s current senior management will hold the majority (three of five) positions in the senior management of the combined company. As a result of EIP being treated as the acquiring company for financial reporting purposes, if the Merger is consummated, among other things, the historical financial statements of EIP will become the historical consolidated financial statements of the combined company.

The unaudited pro forma condensed combined financial information was prepared in accordance with Article 11 of Regulation S-X. The unaudited pro forma condensed combined balance sheet data assumes that the Merger took place on December 31, 2022 and combines the EIP and Diffusion historical balance sheets on December 31, 2022. The unaudited pro forma condensed combined statements of operations data assumes that the Merger took place as of January 1, 2022 and combines the historical results of EIP and Diffusion for the year ended December 31, 2022. The historical financial statements of EIP and Diffusion, which are included elsewhere in this proxy statement/prospectus/information statement, have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical audited financial statements of EIP and Diffusion for the years ended December 31, 2022 and December 31, 2021, which are or included elsewhere in this proxy statement/prospectus/information statement.

In the unaudited pro forma combined condensed financial statements, the Merger has been accounted for as a reverse recapitalization under GAAP because the assets of Diffusion at the Effective Date are expected to be primarily cash, cash equivalents and marketable securities. The unaudited pro forma condensed combined financial statements are based on the assumptions and adjustments that are described in the accompanying notes. The actual amounts recorded as of the completion of the Merger may differ materially from the information presented in these unaudited pro forma condensed combined financial statements as a result of the amount of cash used by Diffusion's operations between the signing of the Merger Agreement and the closing of the Merger; the timing of the closing of the Merger; and other changes in Diffusion's assets and liabilities that occur prior to the completion of the Merger.

In addition, the unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the Merger. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma condensed combined financial information. Furthermore, accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. While this unaudited pro forma condensed combined financial information assumes no material differences, the accounting policies of Diffusion may materially vary from those of EIP. Following consummation of the Merger, management will conduct a final review of Diffusion's accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Diffusion's results of operations or reclassification of assets or liabilities to conform to EIP's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

Accordingly, the unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations in future periods or the results that actually would have been realized had EIP and Diffusion been a combined company during the specified period and may not be useful in predicting the future consolidated results of operations or financial position.

Unaudited Pro Forma Condensed Combined Balance Sheet
As of December 31, 2022

	EIP	Diffusion	Transaction Adjustments	Notes	Pro Forma Combined
Assets					
Current assets:					
Cash and cash equivalents	\$ 4,093,579	\$ 10,113,706	\$ (7,679,622)	A	\$ 6,527,663
Marketable securities	-	12,408,940	-		12,408,940
Prepaid expenses, deposits and other current assets	64,127	112,406	-		176,533
Total assets	\$ 4,157,706	\$ 22,635,052	\$ (7,679,622)		\$ 19,113,136
Liabilities and Stockholders' Equity (Deficit)					
Current liabilities:					
Accounts payable	\$ 97,302	\$ 1,127,782	\$ -		\$ 1,225,084
Accrued expenses and other current liabilities	644,252	1,289,554	(625,963)	B	1,307,843
Convertible note	12,414,000	-	(12,414,000)	C	-
Total liabilities	13,155,554	2,417,336	(13,039,963)		2,532,927
Convertible preferred stock	24,287,211	-	(24,287,211)	D	-
Stockholders' equity (deficit):					
Common stock \$0.001 par value	4,502	2,040	2,432	E	8,974
Additional paid-in capital	18,979,355	165,847,590	(115,986,794)	E	68,840,151
Accumulated other comprehensive loss	-	(35,375)	35,375	E	-
Accumulated deficit	(52,268,916)	(145,596,539)	145,596,539	E	(52,268,916)
Total stockholders' equity (deficit)	(33,285,059)	20,217,716	29,647,552		16,580,209
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 4,157,706	\$ 22,635,052	\$ (7,679,622)		\$ 19,113,136

See accompanying notes to the unaudited pro forma condensed combined financial statements.

**Unaudited Pro Forma Condensed Combined Statements of Operation
For the Year Ended December 31, 2022**

	EIP	Diffusion	Transaction Adjustments	Notes	Pro Forma Combined
Operating expenses:					
Research and development	\$ 1,336,469	\$ 7,237,165	\$ -		\$ 8,573,634
General administrative	2,139,065	8,735,015	-		10,874,080
Loss from operations	(3,475,534)	(15,972,180)	-		(19,447,714)
Non-operating income (expense):					
Interest income, net	61,639	380,752	-		442,391
Other expense, net	(2,389,152)	-	2,389,000	F	(152)
Net Loss	<u>\$ (5,803,047)</u>	<u>\$ (15,591,428)</u>	<u>\$ 2,389,000</u>		<u>\$ (19,005,475)</u>
Net loss per share, basic and diluted	<u>\$ (1.29)</u>	<u>\$ (7.65)</u>			<u>\$ (2.12)</u>
Weighted average common shares outstanding, basic and diluted	<u>4,501,652</u>	<u>2,038,891</u>	<u>2,433,366</u>	G	<u>8,973,909</u>

See accompanying notes to the unaudited pro forma condensed combined financial statements.

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION**1. Description of Transactions***Merger Transaction*

On March 30, 2023, Diffusion, Merger Sub, and EIP entered into the Merger Agreement, pursuant to which, among other things, and subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will merge with and into EIP at the Effective Time, with EIP continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Diffusion. In connection with the Merger, Diffusion intends to change its corporate name from “Diffusion Pharmaceuticals Inc.” to “CervoMed Inc.”

At the Effective Time, all shares of EIP Common Stock outstanding immediately prior to the Effective Time, after giving effect to the conversion of EIP Preferred Stock and the EIP Convertible Notes and excluding certain excluded and dissenting shares, will be converted into the right to receive approximately 9.0 million shares of Diffusion Common Stock in the aggregate, based on an estimated Exchange Ratio of 0.1860, which is based on an assumption that Diffusion’s net cash at the closing of the Merger is between \$13.5 million and \$14.5 million and is subject to certain adjustments, including the final determination of Diffusion’s net cash at closing. This Exchange Ratio is an estimate only and the final exchange ratio will be determined pursuant to a formula described in more detail in the Merger Agreement. Accordingly, because Diffusion’s final net cash will not be determined until the closing, Diffusion stockholders cannot be certain of the exact number of shares that will be issued to EIP stockholders when Diffusion stockholders vote on the proposals at the special meeting.

In addition, (i) each EIP Option granted under the EIP Plan, whether vested or unvested, that is outstanding immediately prior to the Effective Time will be assumed by Diffusion and converted into an option to purchase shares of Diffusion Common Stock, on the same terms and conditions as were applicable to such EIP Option immediately prior to the Effective Time and (ii) each EIP warrant that is outstanding and unexercised immediately prior to the Effective Time will be assumed by Diffusion and converted into and become a warrant to purchase Diffusion Common Stock, in each case, with the number of underlying shares and exercise price adjusted to give effect to the Exchange Ratio.

Immediately following the Effective Time, former EIP stockholders are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and stockholders of Diffusion as of immediately prior to the Effective Time are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, in each case, on a fully-diluted basis as calculated in accordance with the Merger Agreement and assuming that Diffusion's net cash at the closing of the Merger is between \$13.5 million and \$14.5 million.

Conversion of EIP Convertible Notes

Immediately prior to the Effective Time, EIP's \$12.4 million convertible notes will convert into EIP Common Stock that will subsequently be converted into the right to receive shares of Diffusion Common Stock upon completion of the Merger. The estimated Exchange Ratio was calculated as of the date of the Merger Agreement using an assumed conversion price of \$3.00. The actual conversion price will be determined by EIP and the noteholders at a later date prior to the Closing and may differ significantly from the assumed conversion price.

Conversion of EIP Convertible Preferred Stock

Immediately prior to the Effective Time, EIP Preferred Stock will convert into EIP Common Stock that will subsequently be converted into the right to receive shares of Diffusion Common Stock at the Effective Time.

2. Basis of Presentation

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC. The unaudited pro forma condensed combined balance sheet as of December 31, 2022 is presented as if the merger had been completed on December 31, 2022. The unaudited pro forma condensed combined statements of operation for the year ended December 31, 2022 assumes that the merger occurred on January 1, 2022, and combines the historical results of EIP and Diffusion.

For accounting purposes, EIP is considered to be the acquiring company and the Merger will be accounted for as a reverse recapitalization of Diffusion by EIP because at Effective Time, the primary pre-combination assets of Diffusion will be cash and cash equivalents and prepaid and other assets. The exchange ratio was initially estimated at the time of the execution of the Merger Agreement to be 0.1860 shares of Diffusion Common Stock for each share of EIP capital stock and is subject to adjustment prior to the closing for, among other things, Diffusion's net cash at the cash determination time. Because Diffusion's final net cash will not be determined until the closing, and because the number of shares of Diffusion Common Stock issuable to EIP stockholders is determined based on, among other things, Diffusion's final net cash, Diffusion stockholders cannot be certain of the exact number of shares that will be issued to EIP stockholders when Diffusion stockholders vote on the proposals at the Diffusion special meeting. The exchange ratio referenced above is an estimate only and the final Exchange Ratio will be determined pursuant to a formula described in more detail in the section titled "*The Merger Agreement—Merger Consideration*" in this proxy statement/prospectus/information statement. The final Exchange Ratio will be determined based on a net cash calculation prior to the closing, the actual Exchange Ratio will vary based on the net cash calculation prior to the closing as described above and that difference could be material, and as such, the estimated exchange ratio reflected in these unaudited pro forma condensed combined financial statements does not purport to represent what the actual Exchange Ratio will be when the Merger is completed. Holding all other assumptions set forth herein the same, (i) if Diffusion's net cash at the closing of the Merger is equal to \$12.5 million, the Exchange Ratio would be approximately 0.1922 and (ii) if Diffusion's net cash at the closing of the Merger is equal to \$15.5 million, the Exchange Ratio would be approximately 0.1815.

Under reverse recapitalization accounting, the assets and liabilities of Diffusion will be recorded at their carrying values. No goodwill or intangible assets are to be recognized. The historical financial statements of EIP and Diffusion, which are provided elsewhere in this proxy statement/prospectus/information statement, have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

Immediately prior to the Effective Time, EIP Preferred Stock will convert into EIP Common Stock that will subsequently be converted into the right to receive shares of Diffusion Common Stock upon the Effective Time.

Immediately prior to the Effective Time, EIP's convertible notes, which total \$12.4 million in principal and interest in the aggregate, will convert into EIP Common Stock that will subsequently be converted into the right to receive shares of Diffusion Common Stock following the Effective Time.

To the extent there are significant changes to the business following completion of the merger, the assumptions and estimates set forth in the unaudited pro forma condensed combined financial statements could change significantly. Accordingly, the pro forma adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted following the completion of the Merger. There can be no assurances that these additional analyses will not result in material changes to the estimates.

3. Pro Forma Adjustments

The pro forma adjustments were based on the preliminary information available at the time of the preparation of the unaudited pro forma condensed combined financial information. The unaudited pro forma condensed combined financial information, including the notes thereto, are qualified in their entirety by reference to, and should be read in conjunction with, the separate historical audited financial statements of EIP and Diffusion for the years ended December 31, 2022 and December 31, 2021 which are included elsewhere in this proxy statement/prospectus/information statement.

Unaudited Pro forma Condensed Combined Balance Sheet Transaction Adjustments

A Reflects (i) payment of total estimated unpaid transaction costs and (ii) payment of severance costs upon consummation of the merger.

	EIP	Diffusion	Total
Payment of transaction costs	\$ (1,250,000)	\$ (5,034,709)	\$ (6,284,709)
Payment of severance costs	-	(1,394,913)	(1,394,913)
Pro forma adjustment	<u>\$ (1,250,000)</u>	<u>\$ (6,429,622)</u>	<u>\$ (7,679,622)</u>

B Reflects payment of total estimated unpaid transaction costs as of December 31, 2022 in connection with the merger:

	EIP	Diffusion	Total
Unpaid transaction costs as of December 31, 2022	\$ -	\$ (625,963)	\$ (625,963)
Pro forma adjustment	<u>\$ -</u>	<u>\$ (625,963)</u>	<u>\$ (625,963)</u>

C Immediately prior to closing of the Merger, the EIP's Convertible Note will convert into EIP Common Stock that will subsequently be converted into the right to receive shares of Diffusion Common Stock upon closing of the Merger.

D Immediately prior to closing of the Merger, the EIP's Preferred Stock will convert into EIP Common Stock that will subsequently be converted into the right to receive shares of Diffusion Common Stock upon closing of the Merger.

E To record the (i) Exchange Ratio adjustment to EIP Common Stock outstanding, (ii) conversion of EIP Preferred Stock into EIP Common Stock, (iii) automatic conversion of the EIP Convertible Notes into EIP Common Stock, (iv) elimination of Diffusion's historical equity carrying value, (v) issuance of shares of common stock of the continuing company to EIP shareholders, (vi) recording of transaction and severance costs:

	Common stock		Additional paid-in capital	Accumulated Other Comprehensive Income	Accumulated deficit	Total
	Shares	Amount				
EIP's adjusted common stock outstanding in connection with the exchange ratio	837,514	\$ (3,664)	\$ 3,664	\$ -	\$ -	\$ -
Issuance of common stock upon conversion and settlement of EIP's convertible preferred shares and convertible notes	6,095,084	6,095	36,695,116	-	-	36,701,211
Elimination of Diffusion's historical carrying values	-	(2,040)	(145,629,874)	35,375	145,596,539	-
Issuance of shares of common stock of the continuing company to Diffusion shareholders	2,041,311	2,041	(2,041)	-	-	-
Payment of transaction costs and severance expenses	-	-	(7,053,659)	-	-	(7,053,659)
Pro forma adjustment	<u>8,973,909</u>	<u>\$ 2,432</u>	<u>\$ (115,986,794)</u>	<u>\$ 35,375</u>	<u>\$ 145,596,539</u>	<u>\$ 29,647,552</u>

Unaudited Pro forma Condensed Combined Statement of Operations Transaction Adjustments

- F Elimination of change in fair value associated with the EIP Convertible Notes upon conversion into common stock as of January 1, 2022.
- G The pro forma combined basic and diluted loss per share have been adjusted to reflect the pro forma net loss for the year ended December 31, 2022. In addition, the number of shares used in calculating the pro forma combined basic and diluted net loss per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding as of the closing. The following table sets forth the calculation of the pro forma weighted average number of common shares outstanding—basic and diluted.

	Year ended December 31, 2022
Elimination of historical Diffusion weighted average shares	(2,038,891)
Effect of applying estimated exchange ratio to Diffusion Common Stock	(3,664,138)
Issuance of common stock upon conversion and settlement of EIP Preferred Stock and EIP Convertible Notes	6,095,084
Issuance of shares of common stock of the combined company to Diffusion stockholders	2,041,311
	<u>2,433,366</u>

DESCRIPTION OF DIFFUSION CAPITAL STOCK

Diffusion Capitalization

Diffusion's authorized capital stock consists of 1,000,000,000 shares of Diffusion Common Stock, par value \$0.001 per share, and 30,000,000 shares of preferred stock, par value \$0.001 per share, all of which remains undesignated. The following summary is qualified in its entirety by reference to Diffusion's certificate of incorporation, as amended, and bylaws, as amended, copies of which have been filed as exhibits to the registration statement of which this proxy statement/prospectus/information statement is part.

The Reverse Split of Diffusion Common Stock, if any, described in the Reverse Split Proposal, if approved by the affirmative vote of holders of a majority of Diffusion Common Stock outstanding on the record date for the Diffusion special meeting, is expected to occur immediately prior to the Merger and prior to issuance of shares of Diffusion Common Stock to EIP. As a result, the issuance of shares of Diffusion Common Stock to EIP is not expected to exceed the authorized shares of Diffusion Common Stock.

Common Stock

The following description is based on relevant portions of the DGCL and Diffusion's certificate of incorporation. This summary is a description of the material terms of, and is qualified in its entirety by, reference to Diffusion's certificate of incorporation, a copy of which is filed as an exhibit to this proxy statement/prospectus/information statement.

Authorized. Diffusion is authorized to issue 1,000,000,000 shares of Diffusion Common Stock, of which 2,039,557 shares were issued and outstanding as of December 31, 2022. Diffusion may amend from time-to-time Diffusion's certificate of incorporation to increase the number of authorized shares of Diffusion Common Stock. Any such amendment would require the approval of the holders of a majority of the voting power of the shares entitled to vote thereon.

Voting Rights. For all matters submitted to a vote of stockholders, each holder of Diffusion Common Stock is entitled to one vote for each share registered in the holder's name on Diffusion's books. Diffusion Common Stock does not have cumulative voting rights. At all meetings of the stockholders, except where otherwise provided by law, Diffusion's certificate of incorporation or Diffusion's bylaws, the presence, virtually or by proxy duly authorized, of the holders of a majority of the outstanding shares of Diffusion Common Stock entitled to vote constitutes a quorum for the transaction of business. Except as otherwise provided by law or by Diffusion's certificate of incorporation or Diffusion's bylaws in all matters other than the election of directors, the affirmative vote of the majority of shares of Diffusion Common Stock present virtually or by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by law, Diffusion's certificate of incorporation or Diffusion's bylaws, directors are elected by a plurality of the votes of the shares of Diffusion Common Stock present virtually or by proxy at the meeting and entitled to vote generally on the election of directors.

Dividends. Subject to limitations under Delaware law and any preferences that may be applicable to any then outstanding preferred stock, holders of Diffusion Common Stock are entitled to receive ratably those dividends, if any, as may be declared by Diffusion's board of directors out of legally available funds.

Liquidation. Upon Diffusion's liquidation, dissolution or winding up, the holders of Diffusion Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of the company, subject to any prior rights of any preferred stock then outstanding.

Fully Paid and Non-assessable. All shares of outstanding Diffusion Common Stock are fully paid and non-assessable and any additional shares of Diffusion Common Stock that Diffusion issues will be fully paid and non-assessable.

Other Rights and Restrictions. Holders of Diffusion Common Stock do not have preemptive or subscription rights, and they have no right to convert their Diffusion Common Stock into any other securities. There are no redemption or sinking fund provisions applicable to Diffusion Common Stock. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of preferred stock which Diffusion may designate in the future. Diffusion's certificate of Incorporation and bylaws do not restrict the ability of a holder of Diffusion Common Stock to transfer the holder's shares of Diffusion Common Stock.

Listing. Diffusion Common Stock is quoted on the Nasdaq Capital Market under the symbol "DFFN." As of , 2023 there were record holders of Diffusion Common Stock.

Transfer Agent and Registrar. The transfer agent and registrar for Diffusion Common Stock is Computershare Investor Services, LLC, P.O. Box 43078, Providence, RI 02940-3078, telephone number: 1-800-942-5909.

Preferred Stock

Diffusion's certificate of incorporation authorizes Diffusion's board of directors to provide for the issuance of up to 30,000,000 shares of preferred stock in one or more series. Diffusion's board of directors is authorized to classify or reclassify any unissued portion of our authorized shares of preferred stock to provide for the issuance of shares of other classes or series, including preferred stock in one or more series. Diffusion may issue preferred stock from time to time in one or more classes or series, with the exact terms of each class or series established by our board. Without seeking stockholder approval, Diffusion's board of directors may issue preferred stock with voting and other rights that could adversely affect the voting power of the holders of Diffusion Common Stock. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of Diffusion Common Stock.

The rights, preferences, privileges and restrictions of the preferred stock of each series will be fixed by the certificate of designation relating to each series. A prospectus supplement relating to each series will specify the terms of the preferred stock, including, but not limited to:

- the distinctive designation and the maximum number of shares in the series;
- the terms on which dividends, if any, will be paid;
- the voting rights, if any, on the shares of the series;
- the terms and conditions, if any, on which the shares of the series shall be convertible into, or exchangeable for, shares of any other class or classes of capital stock;
- the terms on which the shares may be redeemed, if at all;
- the liquidation preference, if any; and
- any or all other preferences, rights, restrictions, including restrictions on transferability, and qualifications of shares of the series.

The issuance of preferred stock may delay, deter or prevent a change in control. No shares of preferred stock are issued or outstanding, and Diffusion has no present plan to issue any shares of preferred stock.

Diffusion will describe the specific terms of a particular series of preferred stock in the prospectus supplement relating to that series. The description of preferred stock above and the description of the terms of a particular series of preferred stock in the prospectus supplement are not complete. Refer to the applicable certificate of designation for complete information. The prospectus supplement will contain a description of U.S. federal income tax consequences relating to the preferred stock.

Anti-Takeover Provisions of Diffusion's Certificate of Incorporation, Bylaws and Delaware Law

Diffusion's certificate of incorporation and Diffusion's bylaws impose certain anti-takeover provisions and make the Delaware Chancery Court the exclusive forum for certain stockholder actions, which may make the acquisition of Diffusion, a proxy contest, or the nomination of a director candidate by a stockholder more difficult than such actions would be in the absence of such provisions. These provisions include the items described below.

Filling Vacancies

Diffusion's bylaws provide that only Diffusion's board of directors has the right to fill a vacancy on Diffusion's board of directors created by an expansion or by the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on Diffusion's board of directors.

Meetings of Stockholders

Diffusion's bylaws provide that only the Chairman of Diffusion's board of directors, Diffusion's Chief Executive Officer, or a majority of its directors are authorized to call a special meeting of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Diffusion's bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Preferred Stock

Diffusion's certificate of incorporation provides for 30,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable Diffusion's board of directors to discourage an attempt to obtain control of Diffusion by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, Diffusion's board of directors were to determine that a takeover proposal is not in the best interests of Diffusion's stockholders, the Diffusion's board of directors may issue undesignated preferred stock without stockholder approval in one or more private offerings or other transactions, the terms of which may be established and shares of which may be issued without stockholder approval (notwithstanding any requirements imposed by the SEC or any exchange on which Diffusion Common Stock may now or in the future trade), which may include rights superior to the rights of the holders of Diffusion Common Stock and which may dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, Diffusion's certificate of incorporation grants Diffusion's board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of Diffusion Common Stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of Diffusion.

Amendment to Diffusion's Bylaws

Diffusion's bylaws may be amended, restated, or repealed by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of 66 2/3% of the outstanding shares entitled to vote on the amendment.

Advance Notice Requirements

Diffusion's bylaws establish advance notice procedures with respect to any nominations for election to Diffusion's board of directors or for proposing matters that can be acted upon by stockholders at any meeting of stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to Diffusion's Secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at Diffusion's principal executive offices not less than 90 days (or, if Diffusion calls a special meeting of stockholders for the purpose of electing one or more directors to its board of directors, not later than the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by Diffusion's board of directors to be elected at such meeting) nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Diffusion's bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Choice of Forum

Diffusion's bylaws provide that, unless Diffusion consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for certain actions, including derivative actions brought on Diffusion's behalf, stockholder actions claiming breaches of a fiduciary duty owed by any of Diffusion's directors or officers, and claims arising under Diffusion's organizational documents, in each case, subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Although this provision would not apply to any stockholder claims under the Exchange Act, there is uncertainty regarding whether a court would enforce such a forum selection provision as written to stockholder claims under the Securities Act. Nevertheless, this forum selection provision may limit Diffusion's stockholders' ability to obtain a favorable judicial forum for disputes with Diffusion or its directors, officers, employees, or agents, which may discourage lawsuits against Diffusion and such persons. The limitations on certain stockholder rights imposed by these provisions could also depress the trading price of Diffusion Common Stock.

Delaware Anti-Takeover Law

Diffusion is subject to Section 203 of the DGCL. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers of the corporation and (b) shares issued under employee stock plans under which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

COMPARISON OF RIGHTS OF HOLDERS OF DIFFUSION STOCK AND EIP STOCK

General

EIP and Diffusion are both incorporated under the laws of the State of Delaware. The rights of EIP stockholders and Diffusion stockholders are generally governed by the DGCL. Upon completion of the Merger, EIP stockholders will become Diffusion stockholders, and their rights will be governed by the DGCL, the bylaws of Diffusion, as amended, and the certificate of incorporation of Diffusion, as amended.

The material differences between the current rights of EIP stockholders under EIP's amended and restated certificate of incorporation and bylaws and their rights as Diffusion stockholders, after the Merger, under Diffusion's certificate of incorporation, as amended, and its bylaws, as amended, both as will be in effect immediately following the completion of the Merger, are summarized below. The summary below does not purport to be complete and is subject to, and qualified in its entirety by reference to, the DGCL and the governing corporate instruments that are subject to amendment in accordance with their terms. You should carefully read this entire document and the other referenced documents, including the governing corporate instruments, for a more complete understanding of the differences between being a stockholder of EIP or Diffusion before the Merger and being a Diffusion stockholder following the completion of the Merger. For more information on how to obtain these documents, see the section titled "*Where You Can Find More Information*" beginning on page 298.

Authorized Capital Stock

EIP

EIP's amended and restated certificate of incorporation authorizes the issuance of up to 36,000,000 shares of common stock, \$0.001 par value per share, and 28,941,797 shares of preferred stock, \$0.001 par value per share (EIP Preferred Stock), of which 17,033,883 shares are designated Series A-1 Preferred Stock, 2,916,686 shares are designated Series A-2 Preferred Stock, and 8,991,228 shares are designated Series B Preferred Stock. The EIP Series A-1 Preferred Stock and EIP Series A-2 Preferred Stock are together referred to herein as EIP Series A Preferred Stock.

Diffusion

Diffusion's authorized capital stock consists of 1,000,000,000 shares of common stock, \$0.001 par value per share, and 30,000,000 shares of preferred stock, \$0.001 par value per share.

The Merger Agreement contemplates an amendment to Diffusion's certificate of incorporation, as amended, in connection with the closing of the Merger to implement the reverse stock split.

Conversion Rights and Protective Provisions

EIP

The amended and restated certificate of incorporation of EIP provides that each holder of shares of EIP Preferred Stock shall, subject to certain conditions, have the right to convert such shares into shares of EIP Common Stock at any time in accordance with the amended and restated certificate of incorporation of EIP. Each share of EIP Preferred Stock is convertible into one share of EIP Common Stock. The applicable conversion price per share of each series of EIP Preferred Stock is subject to further adjustment if EIP issues additional shares of EIP Common Stock (or options or convertible securities convertible into EIP Common Stock) at a price per share below the applicable conversion price per share of a series of EIP Preferred Stock, subject to certain customary exceptions. The current conversion prices of the EIP Preferred Stock are \$0.09 for the EIP Series A-1 Preferred Stock, \$1.44 for the EIP Series A-2 Preferred Stock, and \$2.28 for the EIP Series B Preferred Stock.

The amended and restated certificate of incorporation of EIP provides that for so long as at least 1,000 shares of EIP Preferred Stock shall be outstanding, EIP shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without the written consent or affirmative vote of the holders of a majority of the outstanding shares of (i) EIP Series A Preferred Stock, voting as a single class and on an as-converted to EIP Common Stock basis and (ii) EIP Series B Preferred Stock, voting as a single class and on an as-converted to EIP Common Stock basis, given in writing or by vote at a meeting: (a) (i) liquidate, dissolve or wind-up the business and affairs of EIP or (ii) effect any merger or consolidation or any other Deemed Liquidation Event (as defined in EIP's amended and restated certificate of incorporation), or consent to (a) (i) or (a) (ii); (b) amend, alter or repeal any provision of EIP's amended and restated certificate of incorporation or bylaws; (c) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of EIP, the payment of dividends and rights of redemption; (d) increase the authorized number of shares of the Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock of EIP unless the same ranks junior to the EIP Preferred Stock with respect to the distribution of assets on the liquidation dissolution or winding up of EIP, the payment of dividends and rights of redemption; (e) (i) reclassify, alter or amend any existing security of EIP that is *pari passu* to the EIP Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of EIP, the payment of dividends and rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the EIP Preferred Stock in respect of any such right, preference or privilege or (ii) reclassify, alter or amend any existing security of EIP that is junior to the EIP Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of EIP, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or *pari passu* with any of the EIP Preferred Stock in respect of any such right, preference or privilege; (f) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of EIP other than (i) redemptions of or dividends or distributions on the EIP Preferred Stock as expressly authorized in EIP's amended and restated certificate of incorporation, (ii) dividends or other distributions payable on the common stock of EIP solely in the form of additional shares of common stock of EIP, and (iii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for EIP or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then current fair market value thereof; (g) create, or authorize the creation of, or issue, or authorize the issuance of any debt security, or permit any subsidiary to take such action with respect to any debt security, if the aggregate indebtedness of EIP and its subsidiaries for borrowed money following such action would exceed \$2,000,000 other than equipment leases or bank lines of credit; (h) create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more subsidiaries) by EIP, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of EIP, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or a series of related transactions) of all or substantially all of the assets of such subsidiary; and (i) increase or decrease the authorized number of directors constituting EIP's board of directors.

Diffusion

All preferences, voting powers, relative, participating, optional or other special rights and privileges, and qualifications, limitations, or restrictions of the holders of Diffusion Common Stock are expressly made subject and subordinate to those that may be fixed with respect to any shares of the Diffusion preferred stock.

Diffusion board of directors is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish for each such series the number of shares to be included in each series, the voting powers, full or limited, of the shares of such series, or that such shares shall have no voting powers, and the designations, preferences and relative, participating, optional or other special rights, if any, of the shares of such series, and any of its qualifications, limitations or restrictions. Diffusion's Board can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding. Diffusion's Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock.

Number of Directors

EIP

EIP's bylaws provide that the number of directors shall be set from time to time by EIP's board of directors or by the stockholders at the annual meeting or at any special meeting of stockholders. EIP's amended and restated certificate of incorporation provides for the election of (i) one EIP Series A Preferred Stock director, elected by the holders of record of the shares of EIP Series A Preferred Stock, voting exclusively and as a separate class, so long as such holders continue to own beneficially at least 10,000,000 shares of EIP Series A Preferred Stock and (ii) one EIP Series B Preferred Stock director, elected by the holders of record of the shares of EIP Series B Preferred Stock, voting exclusively and as a separate class, so long as such holders continue to own beneficially at least 4,500,000 shares of EIP Series B Preferred Stock. The holders of record of the shares of EIP Common Stock and of any other class or series of voting stock (including the EIP Series A Preferred Stock and EIP Series B Preferred Stock, exclusively and voting together as a single class on an as-converted basis), are entitled to elect the balance of the total number of directors of EIP.

Diffusion

Diffusion's certificate of incorporation, as amended, and bylaws, as amended, provide that, Diffusion's authorized number of directors shall be determined from time to time by resolution of the Diffusion board of directors. The Diffusion board of directors currently has five members.

Stockholder Nominations and Proposals

EIP

None.

Diffusion

Diffusion's bylaws, as amended, provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the process, form and content of a stockholder's notice.

Classification of Board of Directors

EIP

EIP's amended and restated certificate of incorporation and bylaws do not provide for the division of EIP's board of directors into staggered classes.

Diffusion

Diffusion's certificate of incorporation, as amended, and the Diffusion bylaws, as amended do not provide for the division of the Diffusion board of directors into staggered classes.

Removal of Directors

EIP

EIP bylaws provide that, any director may be removed from EIP's board of directors at any time, with or without cause, by the holders of a majority of the shares then entitled to vote in an election of directors.

The EIP Pharma, Inc. Voting Agreement (the "EIP Voting Agreement"), dated April 2, 2018, as amended, provides that the board of directors shall consist of (1) one individual designated by the holders of a majority of the outstanding shares of EIP Series A Preferred Stock, voting separately as a class, (2) one individual designated by the holders of a majority of the outstanding shares of Series B Preferred Stock, voting separately as a class, (3) two individuals not otherwise Affiliates of EIP or of any Investor of EIP (each as defined in the EIP Voting Agreement) (the "Independent Directors"), each of whom is mutually acceptable to all of the non-Independent Directors; provided, however, any appointment or replacement of an Independent Director shall require the prior written consent of AI New Holdings 12 LLC for so long as it and its Affiliates (as defined in the EIP Voting Agreement) hold at least 4,500,000 shares of EIP Series B Preferred Stock (as adjusted for any stock splits, stock dividends, combinations or recapitalizations), (4) one individual designated by the holders of the outstanding shares of capital stock of EIP, and (5) EIP's chief executive officer. If any director resigns or is removed, they shall be replaced by a person nominated in accordance with the previous sentence. The Voting Agreement will be terminated immediately prior to the Effective Time, without any liability being imposed on the part of Diffusion or the surviving corporation.

Diffusion

Diffusion's bylaws, as amended provide that any director or the entire Board of Directors may be removed, with or without cause, by the affirmative vote of the holders of a majority of the voting power of all of the outstanding shares of Diffusion capital stock then entitled to vote in the election of directors, voting together as a single class.

Vacancies on the Board of Directors

EIP

EIP's bylaws provide that vacancies occurring on its board of directors may be filled by affirmative vote of the majority of directors then in office, even if less than a quorum or the sole remaining director. EIP's amended and restated certificate of incorporation provides that if the holders of the shares of one or more series of voting capital stock fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, then any directorship not so filled shall remain vacant until such time as the holders of the shares of the applicable class or series of voting capital stock entitled to elect a person to fill such directorship so elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of EIP other than by the holders of the shares of the applicable class or series of capital stock entitled to elect a person to fill such directorship, voting exclusively and as a separate class as provided in the EIP amended and restated certificate of incorporation.

Diffusion

Diffusion's bylaws, as amended, provide that, subject to the rights of the holders of any series of preferred stock then outstanding, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Diffusion board of directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum.

Voting Stock

EIP

EIP's amended and restated certificate of incorporation provides that every stockholder shall be entitled to one vote for each share of EIP Common Stock (including all EIP Preferred Stock on an as-converted basis) as of the record date for determining stockholders entitled to vote on a matter, provided that except as otherwise required by law, holders of EIP Common Stock are not entitled to vote on any amendment to EIP's amended and restated certificate of incorporation that relates solely to the terms of one or more outstanding series of EIP Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to EIP's amended and restated certificate of incorporation or pursuant to Delaware law.

Diffusion

The Diffusion Common Stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders.

Cumulative Voting

EIP

EIP's amended and restated certificate of incorporation does not provide for cumulative voting.

Diffusion

Diffusion stockholders do not have cumulative voting rights in the election of directors.

Stockholder Action by Written Consent

EIP

EIP's bylaws provide that any action permitted to be taken at any annual or special meeting of stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Diffusion

Diffusion's bylaws, as amended, provide that any action to be taken at any annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action to be so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Notice of Stockholder Meeting

EIP

EIP's bylaws provide that except as otherwise provided by law or its amended and restated certificate of incorporation, written notice of each annual or special meeting of the stockholders shall be given to each stockholder of record entitled to vote at such meeting not less than 10 and nor more than 60 days before the day of the meeting to each stockholder entitled to vote at such meeting. Every such notice shall state the date, time, and place by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting.

Notices shall be in writing and may be delivered personally at the addresses appearing on EIP's books by depositing such notice in the mail, postage paid, or by sending such notice by courier service, prepaid telegram or mailgram, or telecopy cable, telex, electronic mail, or by other forms of electronic transmission. Notice shall be deemed to be given at the time when the same shall be given. Notice need not be given to any stockholder who submits a written waiver of notice signed by him or her before or after the time stated therein. Attendance of a person at a meeting without protesting prior thereto or at its commencement shall constitute a waiver of notice of such meeting.

Diffusion

Diffusion's bylaws, as amended, provide that written notice, or notice given by electronic transmission, of a meeting of the stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. The notice shall specify the place, date and hour of the meeting, the means of remote communication(s), if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

Notice shall be given (1) if mailed, when the notice is deposited in the U.S. mail, postage prepaid directed to the stockholder at such stockholder's address as it appears on the records of Diffusion and otherwise is given when delivered. Notice need not be given to any stockholder who submits a written waiver of notice, or by electronic transmission by such stockholder, signed by him or her before or after the time stated therein. Attendance of a person or by proxy at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission.

Special Stockholder Meetings

EIP

EIP's bylaws provide that a special meeting of the stockholders may be called at any time by EIP's board of directors pursuant to a resolution adopted by a majority of the total number of directors authorized.

Diffusion

Diffusion's bylaws, as amended, provide that a special meeting of stockholders may be called at any time by Diffusion's board of directors, pursuant to a resolution adopted by a majority of the directors then in office, or the chairperson of the Diffusion board of directors or its Chief Executive Officer.

Indemnification

EIP

EIP intends to enter into separate indemnification agreements with certain of its directors and executive officers, in addition to the indemnification provided for in EIP's amended and restated certificate of incorporation and bylaws. The indemnification agreements and EIP's amended restated certificate of incorporation and bylaws that will be in effect upon the Effective Time require the combined company to indemnify its directors, officers and agents to the fullest extent permitted by Delaware law.

Diffusion

Diffusion's certificate of incorporation, as amended, and bylaws, as amended, provide that to the fullest extent permitted by law, Diffusion is authorized to provide indemnification any person made or threatened to be made a party to an action, suit or proceeding, whether criminal, civil, administrative or investigative, by reason of the fact that he or she, or a person for whom he or she is the legal representative is or was a director, officer, employee or agent of Diffusion, or serves or served at any other enterprise as a director, officer or agent at the request of Diffusion, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with any such action or proceeding. Diffusion shall not be required to indemnify a person in connection with an action or proceeding (or part thereof) initiated by such person unless the proceeding (or part thereof) was authorized by the Diffusion board of directors.

Diffusion has entered into separate indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in Diffusion's certificate of incorporation, as amended and bylaws, as amended.

Amendment of Certificate of Incorporation

EIP

EIP's board of directors and stockholders may amend, alter, change or repeal any provision of EIP's amended and restated certificate of incorporation in a manner prescribed by statute; provided that (i) any such amendment may be subject to the protective provisions described above, (ii) any repeal or modification of Article Ninth of EIP's amended and restated certificate of incorporation shall not adversely affect any right or protection of any director of EIP existing at the time of such repeal or modification or increase the liability of any director of EIP with respect to any acts or omissions of such director occurring prior to, such repeal or modification, and (iii) any amendment, repeal or modification of Article Tenth of EIP's amended and restated certificate of incorporation shall not adversely affect any right or protection of any director, officer or other agent of EIP existing at the time of such amendment, repeal or modification.

Diffusion

The amendment of any of the provisions in Diffusion certificate of incorporation, as amended, and the ability to alter, change or repeal any provision contained in the Diffusion certificate of incorporation, as amended, is reserved by Diffusion in accordance with the DGCL.

Amendment of Bylaws

EIP

Under EIP's amended and restated certificate of incorporation, EIP's board of directors is expressly authorized to make, repeal, alter, amend and rescind any or all of EIP's bylaws, subject to the protective provisions described above. EIP's bylaws provide that the bylaws may be amended, added to, rescinded or repealed by the stockholders or EIP's board of directors, when such power is conferred upon EIP's board of directors by the EIP amended and restated certificate of incorporation.

Diffusion

Diffusion's certificate of incorporation, as amended and bylaws, as amended provide that the Diffusion's board or directors is expressly empowered to adopt, amend or repeal Diffusion's bylaws, as amended. Any adoption, amendment or repeal of the Diffusion bylaws, as amended, by Diffusion's board of directors shall require the approval of a majority of the directors then in office. Diffusion's certificate of incorporation, as amended, and bylaws, as amended, also provide that the Diffusion stockholders shall also have power to adopt, amend or repeal Diffusion's bylaws, as amended; provided, however, that, in addition to any vote of the holders of any class or series of stock of Diffusion required by law or by Diffusion's certificate of incorporation, as amended, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of Diffusion capital stock entitled to vote generally in the election of directors, voting together as a single class.

Forum Selection

EIP

EIP's amended and restated certificate of incorporation provides that unless EIP consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of EIP, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of EIP to EIP or its stockholders, (iii) any action asserting a claim arising against EIP or its directors, officers or employees arising pursuant to any provision of the DGCL or EIP's amended and restated certificate of incorporation or bylaws or (iv) any action asserting a claim against EIP or its directors, officers or employees governed by the internal affairs doctrine.

Diffusion

Diffusion's bylaws, as amended, provide that, unless Diffusion consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on Diffusion's behalf; (ii) any action asserting a breach of fiduciary duty owed by an director, officer, employee or agent of Diffusion to Diffusion or Diffusion's stockholders; (iii) any action asserting a claim against Diffusion arising under the DGCL, its certificate of incorporation, as amended, or its bylaws, as amended; or (iv) any action asserting a claim against Diffusion that is governed by the internal affairs doctrine.

PRINCIPAL STOCKHOLDERS OF DIFFUSION

Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement do not give effect to the Reverse Split described in the Reverse Split Proposal.

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 promulgated under the Exchange Act) of Diffusion Common Stock as of May 5, 2023 for (i) each person or group of affiliated persons known by Diffusion to be the beneficial owner of more than 5% of Diffusion Common Stock, if any, (ii) each of Diffusion's current directors; (iii) each of Diffusion's current named executive officers (as defined in Item 402(a)(3) of Regulation S-K under the Exchange Act); and (iv) all of Diffusion current directors and named executive officers as a group. As of May 5, 2023, to Diffusion's knowledge, no beneficial owner owned 5% or more of the shares of Diffusion Common Stock then outstanding.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of Diffusion Common Stock issuable under restricted stock units, stock options or warrants that are exercisable or convertible within 60 days of May 5, 2023 are deemed outstanding for the purpose of computing the beneficial ownership percentage of the holder thereof but are not deemed outstanding for the purpose of computing the beneficial ownership percentage of any other person. Ownership is based upon information provided by each respective director and officer and public documents filed with the SEC, including Forms 3 and 4, Schedules 13D and 13G and certain other documents, which information may not be accurate as of May 5, 2023.

Unless otherwise indicated and subject to applicable community property laws, to Diffusion's knowledge, each stockholder named in the following table possesses sole voting and investment power over their shares of Diffusion Common Stock, except for those jointly owned with that person's spouse. Unless otherwise indicated below, the address of each person listed on the table is c/o Diffusion Pharmaceuticals Inc., 300 East Main Street, Suite 201, Charlottesville, Virginia 22902.

Name and Address of Beneficial Owner	Shares of Common Stock Beneficially Owned (1)	Common Stock Beneficial Ownership Percentage (2)
Current Directors		
Robert Adams (3)	3,585	*
Robert J. Cobuzzi, Jr., Ph.D. (4)	23,315	1.1%
Mark T. Giles (5)	4,589	*
Jane H. Hollingsworth (6)	4,313	*
Diana Lanchoney, M.D. (7)	3,711	*
Alan Levin (8)	3,535	*
Current Named Executive Officers		
William R. Elder (9)	6,469	*
William K. Hornung (10)	6,917	*
All Current Directors, Director Nominees, and Named Executive Officers as a Group (eight persons) (11)	56,434	2.7%

* Indicates less than 1.0%

1. Includes shares of Diffusion Common Stock held as of May 5, 2023 plus shares of Diffusion Common Stock that may be acquired upon exercise of options, warrants and other rights exercisable within 60 days of May 5, 2023.

2. Based on 2,040,025 shares of Diffusion Common Stock issued and outstanding as of May 5, 2023. The percentage ownership and voting power for each person (or all directors and executive officers as a group) is calculated by assuming (i) the exercise or conversion of all options, RSUs and other convertible securities exercisable or convertible within 60 days of May 5, 2023 held by such person and (ii) the non-exercise and non-conversion of all outstanding options, RSUs and other convertible securities held by all other persons (including our other directors and executive officers).
3. Consists of (a) 34 shares held directly by Mr. Adams, (b) 12 shares held jointly with Mr. Adams' wife, (c) 25 shares held for the benefit of Mr. Adams in his 401(k) retirement account, and (d) 3,514 shares of common stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023.
4. Consists of (a) 1,616 shares held directly by Dr. Cobuzzi and (b) 21,699 shares of Diffusion Common Stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023.
5. Consists of (a) 5 shares held for the benefit of Mr. Giles in his individual retirement account, (b) 1,070 shares held by MTG Investment Holdings, LLC, and (c) 3,514 shares of common stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023. Mr. Giles is the sole member of MTG Investment Holdings, LLC and may be deemed to be the beneficial owner of such securities. Mr. Giles disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.
6. Consists of (a) 1,116 shares held directly by Ms. Hollingsworth, (b) 3,014 shares of common stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023 and (c) 183 shares of common stock issuable upon the future vesting of restricted stock units within 60 days of May 5, 2023.
7. Consists of (a) 3,332 shares of Diffusion Common Stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023 and (b) 232 shares of Diffusion Common Stock issuable upon the vesting of RSUs expected to vest within 60 days of May 5, 2023.
8. Consists of (a) 33 shares held by Mr. Levin directly and (b) 3,502 shares of Diffusion Common Stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023.
9. Consists of (a) 400 shares held directly by Mr. Elder and (b) 6,069 shares of Diffusion Common Stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023.
10. Consists of 917 shares of Diffusion Common Stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023.
11. Includes (a) 51,561 shares of Diffusion Common Stock issuable upon the exercise of options exercisable within 60 days of May 5, 2023 and (b) 415 shares of common stock issuable upon the vesting of RSUs expected to vest within 60 days of May 5, 2023.

PRINCIPAL STOCKHOLDERS OF EIP

The following table sets forth information with respect to the beneficial ownership of EIP Common Stock as of April 1, 2023 by:

- each of EIP's directors;
- each of EIP's named executive officers;
- all of EIP's directors and executive officers as a group; and
- each person, or group of affiliated persons, who was known by EIP to beneficially own more than 5% of EIP Common Stock.

The number of shares beneficially owned by each person, director or executive officer is based on a total of 41,239,198 shares of EIP Common Stock outstanding as of April 1, 2023, assuming the automatic conversion of all outstanding shares of EIP Preferred Stock and the EIP Convertible Notes occurred on such date.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to EIP's Common Stock. Shares of EIP Common Stock subject to options or warrants that are currently exercisable or exercisable within 60 days after April 1, 2023 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investment power with respect to all of the shares of EIP Common Stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o EIP Pharma, Inc., 20 Park Plaza, Suite 424, Boston, Massachusetts 02116.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
AI New Holdings 12 LLC (1)	9,141,669	22.0%
Joshua Boger (2)	5,285,090	12.8%
Trust FBO JGA (3)	2,385,698	5.8%
Trust FBO MGW (4)	2,385,698	5.8%
Named Executive Officers and Directors		
John Alam, M.D. (5)	12,893,827	31.3%
Sylvie Grégoire, Pharm.D. (6)	12,893,827	31.3%
Jeff Poulton (7)	245,164	*
Marwan Sabbagh, M.D (8).	16,667	*
Frank Zavrl (9)	2,519,144	6.1%
Kelly Blackburn (10)	305,470	*
<i>All Executive Officers and Directors as a Group (7 persons) (11)</i>	15,980,272	38.3%

* Represents beneficial ownership of less than 1% of EIP's outstanding stock.

1. Consists of (i) 8,771,930 shares of EIP Common Stock underlying shares of EIP's Series B preferred stock and (ii) 369,739 shares of EIP Common Stock underlying warrants to purchase EIP Common Stock. The address for AI New Holdings 12 LLC is c/o Access Industries, Inc., 730 5th Floor, New York, NY 10019.

2. Consists of (i) 823,407 shares of EIP Common Stock, (ii) 694,652 shares of EIP Common Stock underlying shares of EIP's Series A-2 preferred stock and (iii) 3,767,031 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes. The address for Joshua Boger is 2 Liberty Drive, PH 2F, Boston, MA 02110.
3. Consists of 2,385,698 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock. Trust FBO JGA is one of multiple trusts established by Dr. Alam and his wife, Dr. Grégoire, for the benefit of family members. Dr. Alam and Dr. Grégoire are co-founders and directors of EIP and serve as EIP's President and Chief Executive Officer and Executive Chair, respectively. Dr. Alam and Dr. Grégoire do not possess authority to vote or dispose of the securities held by Trust FBO JGA, and they disclaim beneficial ownership of such securities. The address for Trust FBO JGA is c/o Michel Grégoire, Trustee, 1510 Menlo Drive, Kennesaw, GA 30152.
4. Consists of 2,385,698 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock. Trust FBO MGW is one of multiple trusts established by Dr. Alam and his wife, Dr. Grégoire, for the benefit of family members. Dr. Alam and Dr. Grégoire are co-founders and directors of EIP and serve as EIP's President and Chief Executive Officer and Executive Chair, respectively. Dr. Alam and Dr. Grégoire do not possess authority to vote or dispose of the securities held by Trust FBO MGW, and they disclaim beneficial ownership of such securities. The address for Trust FBO MGW is c/o Michel Grégoire, Trustee, 1510 Menlo Drive, Kennesaw, GA 30152.
5. Consists of (i) 50,000 shares of EIP Common Stock, (ii) 365,670 shares of EIP Common Stock issuable upon the conversion of EIP Convertible Notes, (iii) 6,031,244 shares of common stock underlying shares of Series A-1 preferred stock held by Dr. Alam; and (x) 50,000 shares of EIP Common Stock, (y) 365,670 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (z) 6,031,243 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock held by Dr. Grégoire, who is married to Dr. Alam. Dr. Alam disclaims beneficial ownership of the shares except to the extent of his indirect pecuniary interest therein.
6. Consists of (i) 50,000 shares of EIP Common Stock, (ii) 365,670 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (iii) 6,031,243 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock held by Dr. Grégoire; and (i) 50,000 shares of EIP Common Stock, (ii) 365,670 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (iii) 6,031,244 shares of EIP Common Stock underlying shares of EIP's Series A-1 preferred stock held by Dr. Alam, who is married to Dr. Grégoire. Dr. Grégoire disclaims beneficial ownership of the shares except to the extent of her indirect pecuniary interest therein.
7. Consists of (i) 69,738 shares of EIP Common Stock underlying shares of EIP's Series A-2 preferred stock, (ii) 73,134 shares of EIP Common Stock issuable upon the conversion of the EIP Convertible Notes, and (iii) 102,292 shares of EIP Common Stock underlying options that are exercisable as of April 1, 2023 or will become exercisable within 60 days after such date.
8. Consists of 16,667 shares of EIP Common Stock underlying options that are exercisable as of April 1, 2023 or will become exercisable within 60 days after such date.
9. Consists of (i) (x) 100,000 shares of EIP Common Stock and (y) 826,541 shares of common stock issuable upon the conversion of EIP Convertible Notes held by PENSICO Trust Company, LLC, Custodian FBO Frank E. Zavrl ROTH IRA; (ii) 1,380,610 shares of EIP Common Stock underlying shares of EIP's Series A-2 preferred stock, (iii) 109,701 shares of EIP Common Stock issuable upon the conversion of EIP Convertible Notes held by Paula Zavrl Delaware Dynasty Trust; and (iv) 102,292 shares of common stock underlying options held by Mr. Zavrl that are exercisable as of April 1, 2023 or will become exercisable within 60 days after such date. Mr. Zavrl is the trust investment manager of the Paula Zavrl Delaware Dynasty Trust.
10. Consists of (i) 9,102 shares of EIP Common Stock, (ii) 109,701 shares of EIP Common Stock issuable upon the conversion of EIP Convertible Notes, and (iii) 186,667 shares of EIP Common Stock underlying options that are exercisable as of April 1, 2023 or will become exercisable within 60 days after such date.
11. Includes 407,918 shares of EIP Common Stock underlying options that are exercisable as of April 1, 2023 or will become exercisable within 60 days after such date.

PRINCIPAL STOCKHOLDERS OF THE COMBINED COMPANY

Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement do not give effect to the Reverse Split described in the Reverse Split Proposal.

The following table sets forth information with respect to the beneficial ownership of the combined company's common stock immediately after the Effective Time, based upon (i) the principal stockholders of EIP as of April 1, 2023, (ii) the principal stockholders of Diffusion as of May 5, 2023 and (iii) the estimated Exchange Ratio calculated as of the date of the Merger Agreement (as applicable, the "Presentation Date") by:

- each person, or group of affiliated persons, expected by Diffusion and EIP to become the beneficial owner of more than 5% of the outstanding common stock of the combined company;
- each executive officer and director of the combined company; and
- all of the combined company's executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options that are exercisable within 60 days of the Presentation Date. Shares of common stock issuable pursuant to stock options are deemed outstanding for computing the percentage of the person holding such options and the percentage of any group of which the person is a member but are not deemed outstanding for computing the percentage of any other person. Except as indicated by the footnotes below, the combined company believes, based on the information furnished to it, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Section 13(d) and 13(g) of the Securities Act.

The percentage of shares beneficially owned is based on an assumed 8,974,207 shares of common stock of the combined company outstanding immediately following the closing of the Merger, excluding the effect of the Reserve Split, if any, adjusted as required by the rules promulgated by the SEC to determine beneficial ownership. Other than as described in this proxy statement/prospectus/information statement, neither Diffusion nor EIP know of any arrangements, including any pledge by any person of securities of the combined company.

Under the Exchange Ratio formula in the Merger Agreement, immediately following the Effective Time, former EIP equity holders are expected to own approximately 77.26% of the outstanding shares of Diffusion Common Stock, and equity holders of Diffusion are expected to own approximately 22.74% of the outstanding shares of Diffusion Common Stock, in each case, assuming Diffusion's net cash (as calculated in accordance with the Merger Agreement) at the closing of the Merger is between \$13.5 million and \$14.5 million. The following table and the related notes assume that, at the Effective Time, each share of EIP Common Stock will convert into the right to receive approximately 0.1860 shares of Diffusion Common Stock, based on the estimated Exchange Ratio calculated as of the date of the Merger Agreement. The estimated exchange ratio calculation used herein is based upon Diffusion's and EIP's capitalization as of the Presentation Date and will be adjusted to account for the issuance of any additional shares of Diffusion and EIP Common Stock prior to the closing of the Merger. See "The Merger Agreement—Merger Consideration and Exchange Ratio" beginning on page 146 for more information regarding the Exchange Ratio.

Except as indicated in footnotes to this table, Diffusion and EIP believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock of the combined company shown as beneficially owned by them, based on information provided to Diffusion and EIP by such stockholders and subject to community property laws where applicable.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o EIP Pharma, Inc., 20 Park Plaza, Suite 424, Boston, Massachusetts 02116.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
AI New Holdings 12 LLC (1)	1,700,350	18.8%
Joshua Boger (2)	983,027	11.0%
<i>Named Executive Officers and Directors</i>		
John Alam, M.D. (3)	2,398,252	26.7%
Sylvie Grégoire, Pharm.D. (4)	2,398,252	26.7%
Jeff Poulton (5)	45,601	*
Marwan Sabbagh, M.D (6).	3,100	*
Frank Zavrl (7)	468,561	5.2%
Kelly Blackburn(8)	56,817	*
Jane Hollingsworth, J.D. (9)	4,313	*
Robert J. Cobuzzi, Jr., Ph.D.(10)	23,315	*
William Elder(11)	6,469	*
<i>All Executive Officers and Directors as a Group (9 persons) (12)</i>	<i>3,006,428</i>	<i>33.1%</i>

* Represents beneficial ownership of less than 1% of outstanding stock.

- (1) Consists of (i) 1,631,579 shares of the combined company's common stock and (ii) 68,771 shares of the combined company's common stock underlying warrants to purchase common stock. The address for AI New Holdings 12 LLC is c/o Access Industries, Inc., 730 5th Avenue, 20th Floor, New York, NY 10019.
- (2) Consists of 983,027 shares of the combined company's common stock. The address for Joshua Boger is 2 Liberty Drive, PH 2F, Boston, MA 02110.
- (3) Consists of 1,199,126 shares of the combined company's common stock held by Dr. Alam and 1,199,126 shares of the combined company's common stock held by Dr. Grégoire, who is married to Dr. Alam. Dr. Alam disclaims beneficial ownership of the shares except to the extent of his indirect pecuniary interest therein.

- (4) Consists of 1,199,126 shares of the combined company's common stock held by Dr. Grégoire and 1,199,126 shares of the combined company's common stock held by Dr. Alam, who is married to Dr. Grégoire. Dr. Grégoire disclaims beneficial ownership of the shares except to the extent of her indirect pecuniary interest therein.
- (5) Consists of 26,574 shares of the combined company's common stock and 19,206 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date.
- (6) Consists of 3,100 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date.
- (7) Consists of (i) 256,793 shares of the combined company's common stock held by Mr. Zavrl, (ii) 172,336 shares of the combined company's common stock held by PENSICO Trust Company, LLC, Custodian FBO Frank E. Zavrl ROTH IRA; (iii) 20,404 shares of the combined company's common stock held by Paula Zavrl Delaware Dynasty Trust; and (iv) 19,026 shares of common stock underlying options held by Mr. Zavrl that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date. Mr. Zavrl is the trust investment manager of the Paula Zavrl Delaware Dynasty Trust.
- (8) Consists of 22,097 shares of the combined company's common stock and 34,730 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date.
- (9) Consists of (i) 1,116 shares of the combined company's common stock, (ii) 3,014 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date and (iii) 183 shares of common stock underlying restricted stock units that are expected to vest within 60 days after such date.
- (10) Consists of 1,616 shares of the combined company's common stock and 21,699 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date.
- (11) Consists of 400 shares of the combined company's common stock and 6,069 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date.
- (12) Includes (i) 106,655 shares of common stock underlying options that are exercisable as of the Presentation Date or will become exercisable within 60 days after such date and (ii) 183 shares of common stock underlying restricted stock units that are expected to vest within 60 days after such date.

LEGAL MATTERS

Dechert LLP will pass upon the validity of the Diffusion Common Stock offered by this proxy statement/prospectus/information statement. The material U.S. federal income tax consequences of the Merger will be passed upon for EIP by Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.

EXPERTS

The consolidated financial statements of Diffusion Pharmaceuticals Inc. as of December 31, 2022 and 2021, and for each of the years then ended, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The financial statements of EIP Pharma, Inc. as of December 31, 2022 and 2021 and for the years then ended have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern), and included in this proxy statement/prospectus/information statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Diffusion is subject to the reporting and information requirements of the Exchange Act and, as a result, files, or will file, periodic reports, proxy statements and other information with the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The SEC's internet site can be found at <http://www.sec.gov>. Diffusion also maintains a website at <http://www.diffusion.com> and makes available free of charge through this website Diffusion's annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. Diffusion makes these reports available through Diffusion's website as soon as reasonably practicable after Diffusion electronically files such reports with, or furnishes such reports to, the SEC. The information contained on, or that can be accessed through, Diffusion's website is not a part of this proxy statement/prospectus/information statement.

As of the date of this proxy statement/prospectus/information statement, Diffusion has filed a registration statement on Form S-4 to register with the SEC the Diffusion Common Stock that Diffusion will issue to EIP stockholders in the Merger. This proxy statement/prospectus/information statement is a part of that registration statement and constitutes a prospectus of Diffusion, as well as a proxy statement of Diffusion for its special stockholder meeting and an information statement for the purpose of EIP for its written consent.

This proxy statement/prospectus/information statement does not contain all the information set forth in that registration statement. For further information about Diffusion and the shares of Diffusion Common Stock to be registered in the Merger, you should refer to the registration statement. Statements contained in this proxy statement/prospectus/information statement relating to the contents of any contract, agreement, or other document are not necessarily complete and are qualified in all respects by the complete text of the applicable contract, agreement, or other document, a copy of which has been filed as an exhibit to the registration statement on Form S-4.

This proxy statement/prospectus/information statement does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this proxy statement/prospectus/information statement, or the solicitation of a proxy, in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer, solicitation of an offer or proxy solicitation in such jurisdiction. Neither the delivery of this proxy statement/prospectus/information statement nor any distribution of securities pursuant to this proxy statement/prospectus/information statement shall, under any circumstances, create any implication that there has been no change in the information set forth or incorporated into this proxy statement/prospectus/information statement by reference or in Diffusion's affairs since the date of this proxy statement/prospectus/information statement.

Diffusion has supplied all information contained in this proxy statement/prospectus/information statement relating to Diffusion, and EIP has supplied all information contained in this proxy statement/prospectus/information statement relating to EIP.

If you would like to request documents from Diffusion or EIP, please send a request in writing or by telephone to either Diffusion or EIP at the following addresses:

Diffusion Pharmaceuticals Inc.
300 East Main Street, Suite 201
Charlottesville, Virginia 22902
Telephone: (434) 220-0718
Attn: Corporate Secretary

EIP Pharma, Inc.
20 Park Plaza, Suite 424
Boston, Massachusetts 02116
Telephone: (617) 744-4400
Attn: John Alam

ASSISTANCE AND ADDITIONAL INFORMATION

If you need assistance with submitting a proxy to vote your shares via the Internet, by telephone or by completing your Diffusion proxy card, or have questions regarding the Diffusion special meeting, please contact Alliance Advisors, LLC, the proxy solicitor for Diffusion, at (toll-free), (call collect) or by email at .

OTHER MATTERS

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires Diffusion's directors and executive officers and all persons who beneficially own more than 10 percent of the outstanding shares of Diffusion Common Stock to file with the SEC initial reports of ownership and reports of changes in ownership of Diffusion Common Stock. Directors, executive officers and greater than 10 percent beneficial owners also are required to furnish Diffusion with copies of all Section 16(a) forms they file.

To Diffusion's knowledge, based on a review of the copies of such reports and amendments to such reports furnished to Diffusion with respect to the year ended December 31, 2022, and based on written representations by Diffusion's directors and executive officers, all required Section 16 reports under the Exchange Act for Diffusion's directors, executive officers and beneficial owners of greater than 10 percent of Diffusion Common Stock were filed on a timely basis during the year ended December 31, 2022, except for the following, each of which were not timely filed: a Form 3 relating to Ms. Raven Jaeger's appointment as Chief Regulatory Officer on May 18, 2022, filed on August 26, 2022; and a Form 4 relating to a June 7, 2022 option grant to Ms. Raven Jaeger in connection with such appointment, also filed on August 26, 2022.

Stockholder Proposals to Be Presented at the Next Annual Meeting of Diffusion

Pursuant to Rule 14a-8 of the Exchange Act, some stockholder proposals may be eligible for inclusion in the proxy statement for Diffusion's next annual meeting of the stockholders. For a proposal of a Diffusion stockholder to be considered for inclusion in next year's Diffusion proxy statement, it must be submitted in writing, with the proof of Diffusion stock ownership in accordance with Rule 14a-8 and received by the Corporate Secretary of Diffusion a reasonable time before Diffusion begins to print and send its proxy materials.

Under Diffusion's bylaws, if a Diffusion stockholder wants to submit a proposal for the next annual meeting of stockholders under Rule 14a-8 or wants to nominate candidates for election as directors at a Diffusion annual meeting of stockholders, the Diffusion stockholder must provide timely notice of his or her intention in writing. To be timely, a Diffusion stockholder's notice must be delivered to the Diffusion's Secretary, at Diffusion's principal executive offices, not less than the close of business on the 90th day, nor earlier than the close of business on the 120th day, prior to the first anniversary of the date of the proxy statement delivered to Diffusion's stockholders in connection with the preceding year's annual meeting; provided, however, that in the event (i) the date of Diffusion's annual meeting is advanced more than 30 days prior to or delayed by more than 30 days after the anniversary of the preceding year's annual meeting, (ii) no proxy statement was delivered to Diffusion's stockholders in connection with the preceding year's annual meeting, or (iii) Diffusion did not hold an annual meeting in the preceding year, notice by a Diffusion stockholder to be timely must be so delivered not earlier than the close of business on the 90th day prior to such annual meeting and not later than the close of business on the later of the 60th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. In the event that the number of directors to be elected to Diffusion's board of directors is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased board of directors made by Diffusion at least 70 days prior to the first anniversary of the preceding year's annual meeting (or, if the annual meeting is held more than 30 days before or 30 days after such anniversary date, at least 70 days prior to such annual meeting) a Diffusion stockholder's notice shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to Diffusion's Secretary at Diffusion's principal executive offices not later than the close of business on the 10th day following the day on which such public announcement is first made by Diffusion.

Process Regarding Stockholder Communications with Board

Stockholders may communicate with Diffusion's board of directors or any one particular director by sending correspondence, to its General Counsel and Corporate Secretary via e-mail to proxyrequests@diffusionpharma.com or via mail to 300 East Main Street, Suite 201, Charlottesville, Virginia 22902, with an instruction to forward the communication to Diffusion's board of directors or one or more particular directors. Diffusion's General Counsel and Corporate Secretary will forward promptly all such stockholder communications to Diffusion's board of directors or the one or more particular directors, with the exception of any advertisements, solicitations for periodical or other subscriptions and other similar communications.

Householding of Materials

Some banks, brokers and other nominee record holders may be participating in the practice of “householding” proxy statements and annual reports. This means that only one copy of this proxy statement/prospectus/information statement will be sent to multiple stockholders in each household. Diffusion will deliver promptly a separate copy to any stockholder upon request via e-mail to proxyrequests@diffusionpharma.com or via mail to 300 East Main Street, Suite 201, Charlottesville, Virginia 22902, Attn: General Counsel and Corporate Secretary. Any stockholder who wants to receive separate copies of this proxy statement/prospectus/information statement and annual disclosure documents in the future, or any stockholder who is receiving multiple copies and would like to receive only one copy per household, should contact the stockholder’s bank, broker, or other nominee record holder, or the stockholder may contact Diffusion at the provided address and phone number.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Diffusion Pharmaceuticals Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Diffusion Pharmaceuticals Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

McLean, Virginia
March 24, 2023

DIFFUSION PHARMACEUTICALS INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,113,706	\$ 37,313,558
Marketable securities	12,408,940	—
Prepaid expenses and other current assets	112,406	510,015
Total current assets	<u>22,635,052</u>	<u>37,823,573</u>
Other assets	—	15,578
Total assets	<u>\$ 22,635,052</u>	<u>\$ 37,839,151</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,127,782	\$ 947,495
Accrued expenses and other current liabilities	1,289,554	1,980,189
Total liabilities	<u>2,417,336</u>	<u>2,927,684</u>
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Common stock, \$0.001 par value: 1,000,000,000 shares authorized: 2,039,557 and 2,038,185 shares issued and outstanding at December 31, 2022 and 2021, respectively	2,040	2,038
Additional paid-in capital	165,847,590	164,914,540
Accumulated other comprehensive loss	(35,375)	—
Accumulated deficit	(145,596,539)	(130,005,111)
Total stockholders' equity	<u>20,217,716</u>	<u>34,911,467</u>
Total liabilities and stockholders' equity	<u>\$ 22,635,052</u>	<u>\$ 37,839,151</u>

See accompanying notes to consolidated financial statements.

DIFFUSION PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 7,237,165	\$ 8,499,414
Intangible asset impairment charge	—	8,639,000
General and administrative	8,735,015	7,445,277
Depreciation	—	93,416
Loss from operations	(15,972,180)	(24,677,107)
Other income:		
Interest income	380,752	137,487
Loss before income taxes	(15,591,428)	(24,539,620)
Income tax benefit	—	443,893
Net loss	\$ (15,591,428)	\$ (24,095,727)
Share information:		
Net loss per share of common stock, basic and diluted	\$ (7.65)	\$ (12.38)
Weighted average shares outstanding, basic and diluted	2,038,891	1,946,859
Comprehensive loss:		
Net loss	\$ (15,591,428)	\$ (24,095,727)
Unrealized loss on marketable securities	(35,375)	—
Comprehensive loss	\$ (15,626,803)	\$ (24,095,727)

See accompanying notes to consolidated financial statements.

DIFFUSION PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2022	—	\$ —	2,038,185	\$ 2,038	\$ 164,914,540	\$ —	\$ (130,005,111)	\$ 34,911,467
Sale of Series C preferred stock to related parties	10,000	5,000	—	—	—	—	—	5,000
Conversion of Series C preferred stock to common stock	(10,000)	(5,000)	200	—	5,000	—	—	—
Stock-based compensation expense and vesting of restricted stock units	—	—	1,172	2	928,050	—	—	928,052
Unrealized loss on marketable securities	—	—	—	—	—	(35,375)	—	(35,375)
Net loss	—	—	—	—	—	—	(15,591,428)	(15,591,428)
Balance at December 31, 2022	—	\$ —	2,039,557	\$ 2,040	\$ 165,847,590	\$ (35,375)	\$ (145,596,539)	\$ 20,217,716

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2021	1,280,207	\$ 1,280	\$ 130,722,286	\$ (105,909,384)	\$ 24,814,182
Vesting of restricted stock units	207	—	—	—	—
Sale of common stock	673,171	673	31,093,629	—	31,094,302
Issuance of common stock upon exercise of warrants	84,600	85	2,201,365	—	2,201,450
Stock-based compensation expense	—	—	897,260	—	897,260
Net loss	—	—	—	(24,095,727)	(24,095,727)
Balance at December 31, 2021	2,038,185	\$ 2,038	\$ 164,914,540	\$ (130,005,111)	\$ 34,911,467

See accompanying notes to consolidated financial statements.

DIFFUSION PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (15,591,428)	\$ (24,095,727)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	—	93,416
Loss on disposal of property and equipment	—	51,782
Stock-based compensation expense	928,052	897,260
Abandonment of in-process research and development intangible asset	—	8,639,000
Change in deferred income taxes	—	(443,893)
Amortization of premium and discount on marketable securities	(208,577)	—
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	413,187	(248,997)
Accounts payable, accrued expenses and other current liabilities	(510,348)	605,370
Net cash used in operating activities	(14,969,114)	(14,501,789)
Cash flows from investing activities:		
Cash received from sale of property and equipment	—	4,000
Purchases of marketable securities	(37,985,738)	—
Maturities of marketable securities	25,750,000	—
Net cash (used in) provided by investing activities	(12,235,738)	4,000
Cash flows from financing activities:		
Proceeds from the sale of common stock, net of issuance cost	—	31,094,302
Proceeds from the sale of common stock warrants	—	2,201,450
Proceeds from the sale of preferred stock	5,000	—
Net cash provided by financing activities	5,000	33,295,752
Net (decrease) increase in cash and cash equivalents	(27,199,852)	18,797,963
Cash and cash equivalents at beginning of year	37,313,558	18,515,595
Cash and cash equivalents at end of year	\$ 10,113,706	\$ 37,313,558
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of Series C preferred stock to common stock	\$ 5,000	\$ —
Unrealized loss on marketable securities	\$ 35,375	\$ —
Vesting of restricted stock units	\$ 1,361	\$ 207

See accompanying notes to consolidated financial statements.

**DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

1. Organization and Description of Business

Diffusion Pharmaceuticals Inc., a Delaware corporation, is a biopharmaceutical company historically focused on developing novel therapies that enhance the body's ability to deliver oxygen to areas where it is needed most. The Company's most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including GBM.

On April 18, 2022, the Company effected a 1-for-50 reverse split of its common stock. Any references in the consolidated financial statements and related notes to share or per share amounts give retroactive effect to this reverse stock split.

2. Liquidity

The Company has not generated any revenues from product sales and has historically funded operations primarily from the proceeds of public and private offerings of equity, convertible debt, and convertible preferred stock.

In July 2022, the Company entered into an at-the-market sales agreement (the "2022 Sales Agreement") with BTIG pursuant to which the Company may, from time to time and through BTIG as its agent, sell up to an aggregate of \$20.0 million in shares of the Company's common stock by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. To date, the Company has not sold any shares pursuant to the 2022 Sales Agreement.

On October 25, 2022, the Company announced that its Board authorized a thorough review and evaluation of a range of potential strategic opportunities in the interest of enhancing stockholder value, including transactional opportunities such as a merger, joint venture, licensing, sale, or divestiture of assets. As of the date of this Annual Report, the Board's review and evaluation remains ongoing and there is no assurance the Board's review will result in any transaction being consummated. Depending on the outcome of the Board's strategic review process, the Company may in the future, among other things, (i) pursue a strategic transaction and, if consummated, dedicate its resources primarily to research and development activities related to the transactional counterparty's product candidates, (ii) dedicate its resources primarily to research and development activities related to the Company's existing product candidates, or (iii) elect to pursue a dissolution and liquidation of the Company.

On February 16, 2023, in connection with the ongoing strategic review process and efforts to utilize and preserve assets in a manner that maximizes value for its stockholders, the Company committed to a reduction in force that is expected to impact six of the Company's thirteen current employees. The reduction is a cash preservation measure and impacts employees primarily in the Company's clinical operations function. In connection with the strategic review process and pending its conclusion, the Company has paused significant portions of its TSC development activities, including initiation of the Company's previously announced Phase 2 study of TSC in newly diagnosed GBM patients.

Substantial additional financing will be required by the Company to fund any research and development activities related to the Company's existing or future product candidates. The Company regularly explores alternative means of financing its operations and seeks funding through various sources, including public and private securities offerings, collaborative arrangements with third parties, and other strategic alliances and business transactions. However, as of the date of this Annual Report, the Company does not have any commitments to obtain additional funds and no assurance can be given that any such financing will be available in the future — when needed, in sufficient amounts, on acceptable terms, or at all. If the Company cannot obtain the necessary funding, it may need to, among other things, delay, continue to scale back or eliminate research and development programs, modify its overall development strategy for one or more product candidates (or the Company as a whole) in a manner it would not if sufficient cash resources were available, or cease operations altogether.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
CONTINUED

Operations of the Company are subject to certain additional risks and uncertainties as well, and any one or more of these factors could materially affect the Company's financial condition, future operations and liquidity needs. Many of these risks and uncertainties are outside of the Company's control, including the outcome of its ongoing strategic review process and various internal and external factors that may affect the success or failure of the Company's research and development efforts, the length of time and cost of developing and commercializing the Company's current or future product candidates, whether and when any such product candidates become approved drugs, and how significant a drug's market share will be, if approved, among others.

Subject to the outcome and timing of its ongoing strategic review process, the Company currently expects that its existing cash, cash equivalents and marketable securities as of December 31, 2022 are sufficient to fund its current operations for at least 12 months following the issuance of these financial statements.

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with Generally Accepted Accounting Principles. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification and Accounting Standards Updates of the Financial Accounting Standards Board.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

On an ongoing basis, the Company evaluates its estimates using historical experience and other factors, including the current economic environment. Significant items subject to such estimates are assumptions used for purposes of determining stock-based compensation and accounting for research and development activities. Management believes its estimates to be reasonable under the circumstances. Actual results could differ significantly from those estimates.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash, cash equivalents, marketable securities, and accounts payable approximate fair value due to the short-term nature of those instruments.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash on deposit with multiple financial institutions, the balances of which frequently exceed federally insured limits.

Cash and Cash Equivalents

The Company considers any highly-liquid investments, such as money market funds, with an original maturity of three months or less to be cash equivalents.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Marketable Securities

The Company classifies its marketable securities as available-for-sale, which include commercial paper and U.S. government debt securities with original maturities of greater than three months from date of purchase. The Company considers its marketable securities as available for use in current operations, and therefore classifies these securities as current assets on the consolidated balance sheet. These securities are carried at fair value, with unrealized gains and losses reported in comprehensive loss and accumulated other comprehensive loss within stockholders' equity. Gains or losses on marketable securities sold will be based on the specific identification method.

Reverse Stock Split

On April 18, 2022, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to implement the Reverse Stock Split at a ratio of 1-to-50. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would have been entitled to receive fractional shares of common stock became entitled to receive an amount in cash (without interest or deduction) equal to the fraction of one share to which such stockholder would otherwise be entitled multiplied by \$12.93, representing the split-adjusted average closing price of the Company's common stock on the Nasdaq Capital Market for the five consecutive trading days immediately preceding the effective date of the Reverse Stock Split. Proportional adjustments were made to the Company's outstanding warrants, stock options, and other equity securities, as well as to the reserve of shares available for future issuance under the 2015 Equity Plan, to reflect the Reverse Stock Split, in each case, in accordance with the respective terms thereof.

Intangible Asset

In the third quarter of 2021, the Board of Directors made a determination to no longer dedicate financial resources to the Company's DFN-529 intangible asset and any future internal development efforts were abandoned. In connection with this decision, the Company concluded that DFN-529 was impaired in its entirety and as such, the Company recognized a non-cash impairment charge of \$8.6 million in 2021. The abandonment also resulted in an income tax benefit of \$0.4 million due to the tax effect of the reduction in the deferred tax liability associated with the asset.

Research and Development

Major components of research and development costs include internal research and development (such as salaries and related employee benefits, equity-based compensation, supplies and allocated facility costs) and contracted services (research and development activities performed on the Company's behalf). Costs incurred for research and development are expensed as incurred.

At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the services provided, the Company may record net prepaid or accrued expenses relating to these costs.

Upfront payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered.

Patent Costs

Patent costs, including related legal costs, are expensed as incurred and are recorded within general and administrative expenses in the consolidated statements of operations and comprehensive loss.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Income Taxes

As a corporation, the Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on its income tax return it files, if such a position is more likely than not to be sustained.

FASB ASC Subtopic 740-10, *Accounting for Uncertainty of Income Taxes*, (“ASC 740-10”) defines the criterion an individual tax position must meet for any part of the benefit of the tax position to be recognized in financial statements prepared in conformity with GAAP. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not such tax position will be sustained on examination by the taxing authorities, based solely on the technical merits of the respective tax position. The tax benefits recognized in the financial statements from such a tax position should be measured based on the largest benefit having a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority. In accordance with the disclosure requirements of ASC 740-10, the Company’s policy on income statement classification of interest and penalties related to income tax obligations is to include such items as part of total interest expense and other expense, respectively. The Company adopted ASU No. 2019-12 in the first quarter of 2021 and the adoption did not have a material impact on the Company’s consolidated financial statements.

Stock-based Compensation

The Company measures stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company uses the Black-Scholes Model to value its stock option awards. Estimating the fair value of stock option awards requires management to apply judgment and make estimates, including the volatility of the Company’s common stock, the expected term of the Company’s stock options, the expected dividend yield and the fair value of the Company’s common stock on the measurement date. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

For certain stock option grants, the expected term was estimated using the “simplified method” for employee options as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post vesting employment termination behavior for its stock option grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. During the year ended December 31, 2022, the Company uses the simplified method to estimate the expected term.

For stock price volatility, the Company uses a combination of its own historical stock price and comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company’s history of not paying dividends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the option. The Company accounts for forfeitures in the periods they occur.

Net Loss Per Common Share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during each period. Diluted net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as common stock warrants, stock options and unvested restricted stock that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	December 31,	
	2022	2021
Common stock warrants	111,891	129,989
Stock options	140,040	72,454
Unvested restricted stock units	3,652	5,509
	<u>255,583</u>	<u>207,952</u>

Recently Issued But Not Yet Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses, Measurement of Credit Losses on Financial Instruments* (Topic 326). The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective for the Company as of January 1, 2023. The Company is currently evaluating the impact of this ASU and does not expect that adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

4. Cash, cash equivalents and marketable securities

The following is a summary of the Company's cash and cash equivalents as of the dates indicated:

	December 31,	
	2022	2021
Cash in banking institutions	\$ 1,586,920	\$ 30,308,075
Money market funds	8,526,786	7,005,483
Total	<u>\$ 10,113,706</u>	<u>\$ 37,313,558</u>

The following is a summary of the Company's marketable securities as of December 31, 2022:

	Amortized cost	Unrealized gains	Unrealized losses	Fair Value
Commercial paper	\$ 9,445,220	\$ 263	\$ (21,313)	\$ 9,424,170
U.S. treasury bonds	2,999,095	—	(14,325)	2,984,770
Total	<u>\$ 12,444,315</u>	<u>\$ 263</u>	<u>\$ (35,638)</u>	<u>\$ 12,408,940</u>

The Company did not have any marketable securities as of December 31, 2021. The Company's marketable securities generally have contractual maturity dates between 3 and 12 months. All but one of the Company's marketable securities are in an unrealized loss position at December 31, 2022. Unrealized losses on marketable securities as of December 31, 2022 were \$35,638 and were primarily due to changes in interest rates, and not due to increased credit risks associated with specific securities. Accordingly, no other-than-temporary impairment was recorded for the year ended December 31, 2022 and there were no realized gains or losses recorded during the year ended December 31, 2022.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Fair Value of Financial Instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments be made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Company's financial instruments, including prepaid expense and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The Company follows the provisions of FASB ASC Topic 820, *Fair Value Measurement*, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following table presents the Company's assets that are measured at fair value on a recurring basis:

	Fair value measurement at reporting date		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2022			
Cash equivalents:			
Money market funds	\$ 8,526,786	\$ —	\$ —
Commercial paper	—	—	—
Total cash and cash equivalents	<u>\$ 8,526,786</u>	<u>\$ —</u>	<u>\$ —</u>
Marketable securities:			
Commercial paper	\$ —	\$ 9,424,170	\$ —
US treasury	—	2,984,770	—
Total marketable securities	<u>\$ —</u>	<u>\$ 12,408,940</u>	<u>\$ —</u>
Total financial assets	<u>\$ 8,526,786</u>	<u>\$ 12,408,940</u>	<u>\$ —</u>

The fair values of the Company's Level 2 marketable securities are estimated primarily based on benchmark yields, reported trades, market-based quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, and reference data including market research publications, which represent a market approach. In general, a market approach is utilized if there is readily available and relevant market activity for an individual security. This valuation technique may change from period to period, based on the relevance and availability of market data.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2022	2021
Accrued payroll and payroll related expenses	\$ 131,777	\$ 879,971
Accrued professional fees	552,785	247,704
Accrued clinical studies expenses	475,141	786,579
Other	129,851	65,935
Total	\$ 1,289,554	\$ 1,980,189

7. Stockholders' Equity and Common Stock Warrants

Common Stock Warrants

As of December 31, 2022, the Company had the following warrants outstanding to acquire shares of its common stock:

	Outstanding	Range of exercise price per share			Expiration dates
		\$	-	\$	
Common stock warrants issued in 2018 related to the January 2018 Offering	23,639	\$599.71	-	\$749.76	January 2023
Common stock warrants issued related to the May 2019 Offering	27,648	\$250.09	-	\$306.04	May and December 2024
Common stock warrants issued related to the November 2019 Offering	4,269	\$17.51			November 2024
Common stock warrants issued related to the December 2019 Offering	6,264	\$21.68	-	\$34.92	December 2024 and June 2025
Common stock warrants issued related to the May 2020 Offering	11,424	\$65.65			March 2025
Common stock warrants issued related to the May 2020 Investor Warrant Exercise	4,998	\$29.70			November 2025
Common stock warrants issued related to the February 2021 Offering	33,649	\$64.08			February 2026
	<u>111,891</u>				

During the years ended December 31, 2022 and 2021, 18,077 and 1,071 warrants expired, respectively.

8. Stock-Based Compensation

2015 Equity Plan

The 2015 Equity Plan provides for increases to the number of shares reserved for issuance thereunder each January 1 equal to 4.0% of the total shares of the Company's common stock outstanding as of the immediately preceding December 31, unless a lesser amount is stipulated by the Compensation Committee of the Company's board of directors. Accordingly, 81,582 shares were added to the reserve as of January 1, 2023, which shares may be issued in connection with the grant of stock-based awards, including stock options, restricted stock, restricted stock units, stock appreciation rights and other types of awards as deemed appropriate, in each case, in accordance with the terms of the 2015 Equity Plan. As of December 31, 2022, there were 24,953 shares available for future issuance under the 2015 Equity Plan.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations and comprehensive loss for the periods indicated:

	December 31,	
	2022	2021
Research and development	\$ 215,904	\$ 154,041
General and administrative	712,148	743,219
Total stock-based compensation expense	\$ 928,052	\$ 897,260

The following table summarizes the activity related to all stock options:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate Intrinsic Value
Balance at January 1, 2021	44,738	\$ 407.60		
Granted	36,310	44.66		
Expired	(8,594)	68.48		
Balance at December 31, 2021	72,454	265.91		
Granted	77,088	9.87		
Forfeited	(8,892)	147.28		
Expired	(610)	1,562.92		
Outstanding at December 31, 2022	140,040	126.75	8.5	—
Exercisable at December 31, 2022	74,086	\$ 226.95	7.9	—
Vested and expected to vest at December 31, 2022	140,040	\$ 126.75	8.5	—

The weighted average grant date fair value of stock option awards granted was \$9.87 and \$44.66 during the years ended December 31, 2022 and 2021, respectively. The total fair value of options vested during the years ended December 31, 2022 and 2021 were \$0.8 million and \$0.8 million, respectively. No options were exercised during any of the periods presented. At December 31, 2022, there was \$0.9 million of unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted-average period of 1.5 years.

The grant date fair value of employee stock options is determined using the Black-Scholes Model. The following assumptions were used during the years ended December 31, 2022 and 2021:

	2022		2021	
	5.5	—	5.7	10
Expected term (in years)	5.5	—	5.7	10
Risk-free interest rate	1.7%	—	3.9%	1.3% — 1.7%
Expected volatility	121.4%	—	137.1%	122.6% — 125.8%
Dividend yield	—	—	—	—

Restricted Stock Unit Awards

The Company issues restricted stock ("RSU") to newly elected, non-executive members of the board of directors that vest in six, tri-monthly installments beginning 18 months after the respective grant date. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. RSU expense is recorded on a straight-line basis over the service period.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes activity related to RSU stock-based payment awards:

	Number of Units	Weighted average grant date fair value
Balance at January 1, 2022	5,509	\$ 34.78
Vested ⁽¹⁾	(1,857)	31.41
Outstanding at December 31, 2022	3,652	36.49

(1) The RSUs vested during the year ended December 31, 2022 were settled on a hybrid basis. The Company withheld 685 shares of common stock and, in lieu of delivering such shares, paid the RSU holder an amount in cash equal to the fair market value of such shares on the vesting date, representing the holder's approximate tax liability associated with the vesting.

The Company recognized approximately \$65,000 and \$54,000 in expense related to these units during the years ended December 31, 2022 and 2021, respectively. At December 31, 2022, there was approximately \$0.1 million of unrecognized compensation cost that will be recognized over a weighted average period of 1.3 years.

9. Commitments and Contingencies

Office Space Lease Commitment

As of December 31, 2022, the Company had short-term agreements to utilize membership-based co-working space in both Charlottesville, Virginia and Philadelphia, Pennsylvania. Rent expense related to the Company's short-term agreements for the years ended December 31, 2022 and 2021 was approximately \$18,000 and \$5,000, respectively.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities and contract research organizations, or CROs, to assist in the performance of research and development activities and contract manufacturers to assist with chemistry, manufacturing, and controls related expenses. Expenditures to CROs represent a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Defined Contribution Retirement Plan

The Company has established a 401(k) defined contribution plan that covers all employees who qualify under the terms of the plan. Eligible employees may elect to contribute to the 401(k) Plan up to 90% of their compensation, limited by the IRS-imposed maximum. The Company provides a safe harbor match with a maximum amount of 4% of the participant's compensation. The Company made matching contributions under the 401(k) Plan of approximately \$97,000 and \$75,000 for the years ended December 31, 2022 and 2021, respectively.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Legal Proceedings

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, the former Chief Executive Officer of the Company's legal predecessor under the caption Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys' fees and costs. On December 30, 2014, the Company filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to the Company's petition to compel arbitration and a motion to stay the action. After a related hearing on April 14, 2015, the court granted the Company's petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. On November 19, 2018 at an Order to Show Cause Re Dismissal Hearing, the court found sufficient grounds not to dismiss the case and an arbitration hearing was scheduled, originally for November 2020 but later postponed due to the COVID-19 pandemic and related restrictions on gatherings in the State of California. In addition, following the November 2018 hearing, an automatic stay was placed on the arbitration in connection with the plaintiff filing for personal bankruptcy protection. On October 22, 2021, following a determination by the bankruptcy trustee not to pursue the claims and release them back to the plaintiff, the parties entered into a stipulation to abandon arbitration and return the matter to state court. A case management conference was held on February 23, 2022 at which an initial trial date of May 24, 2023 was set, and the parties have agreed to stipulate to mediation in advance of the trial. On October 20, 2022, the parties filed a joint stipulation to continue the trial and certain deadlines related to the mediation in order to allow plaintiff's counsel to continue to seek treatment for an ongoing medical issue. On November 1, 2022, based on the parties joint stipulation, the court entered an order continuing the trial date to October 25, 2023.

The Company believes the claims in this matter are without merit and is defending itself vigorously. However, at this stage, the Company is unable to predict the outcome and possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company's financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company's consolidated financial position, results of operations and cash flows.

10. Income Taxes

Income tax expense is summarized as follows:

	December 31, 2022	December 31, 2021
Federal	\$ —	\$ (362,150)
State	—	(81,743)
Total	—	(443,893)

Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which differences are expected to reverse.

DIFFUSION PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Significant components of the Company's deferred tax assets for federal income taxes consisted of the following:

Deferred tax assets	December 31, 2022	December 31, 2021
Net operating loss carryforwards	\$ 8,650,404	\$ 6,033,726
Stock option compensation	1,754,906	1,641,354
Orphan Drug credits	1,306,682	647,937
Capitalized start-up costs and other	12,788,834	12,403,925
Valuation allowance	(24,471,392)	(20,726,942)
Deferred tax assets	\$ —	\$ —

The Company does not have unrecognized tax benefits as of December 31, 2022 or December 31, 2021. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

The Company had NOL carryforwards for federal and state income tax purposes at December 31, 2022 and 2021 of approximately:

Combined NOL Carryforwards:	December 31, 2022	December 31, 2021
Federal	\$ 34,116,553	\$ 23,442,045
State	30,727,733	23,436,624

The pre-2018 net operating loss carryforwards have begun to expire for both federal and state income tax purposes. Net operating loss carryforwards post Tax Cuts and Jobs Act of 2017 have an indefinite life. In November 2019, the Company increased the number of shares outstanding resulting in a change of ownership, under the provisions of Internal Revenue Code Section 382 and similar state provisions. These provisions limit the Company's ability to utilize these net operating loss carryforwards to offset future income. The amounts above reflect the amount of NOLs that the Company expects to be able to utilize as a result of the limitation. The Company recorded a 100% valuation allowance of the deferred tax assets as of December 31, 2022 because of the uncertainty of their realization.

A reconciliation of income tax benefit at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements is as follows:

Rate reconciliation:	December 31, 2022	December 31, 2021
Federal tax benefit at statutory rate	(21.0)%	(21.0)%
State tax, net of Federal benefit	(3.9)%	(4.7)%
Orphan drug credit	(4.5)%	(0.4)%
Change in valuation allowance	29.0%	24.3%
Stock compensation	0.4%	—%
Other	—%	—%
Total provision	—%	(1.8)%

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company's 2018 to 2022 tax years remain open and subject to examination. All net operating losses and credits remain subject to review until utilized.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of EIP Pharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of EIP Pharma, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations, changes in convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes to the financial statements (collectively, the financial statements).

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and its total liabilities exceed its total assets. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the auditing standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Convertible Notes

The Company has outstanding convertible notes with an aggregate principal balance of \$11.1 million, as described in Note 9 of the financial statements. The Company has elected the fair value option for the convertible notes in accordance with ASC 825-10, *Financial Instruments*. The Company recorded the convertible notes on its balance sheet at their fair value of \$12.4 million as of December 31, 2022. The Company also recorded a loss on its statement of operations of \$12.4 million to reflect the change in fair value of the convertible notes during the year ended December 31, 2022. The methodology used by the Company to estimate the fair value of the convertible notes at December 31, 2022 was the combination of a zero-coupon bond and a call option. The model used inputs based on certain assumptions, including the estimated term, probability of various outcomes, and market yield.

We identified the valuation of the convertible notes as a critical audit matter because of the complexity of the valuation model, including the judgments made by management in estimating the fair value of the convertible notes. The valuation model used in determining the fair value of the convertible notes include inputs subject to management's judgment, including the time to such event at the date of valuation, estimates of the probability of each conversion event occurring, volatility and the market yield. This required subjective auditor judgment and increased level of effort when performing audit procedures, including the involvement of valuation professionals with specialized skills and knowledge.

Our audit procedures related to the Company's valuation of the convertible notes included the following, among others:

- Obtained and compared the relevant terms of convertible note agreements to inputs and assumptions utilized within management's valuation.
- Evaluated the reasonableness of significant assumptions used to calculate the fair value of the convertible notes, including the estimate of the probability of a qualified financing, initial public offering, non-qualified financing, change in control, SPAC or reverse merger, or liquidation event, and the time to such event.
- With the assistance of our fair value specialists:
 - We tested the appropriateness of the methodology used in estimating the fair value of the convertible notes, including evaluating the reasonableness of the significant assumptions for volatility and market yield; and
 - Tested the mathematical accuracy of management's valuation.

/s/ RSM US LLP

We have served as the Company's auditor since 2017.

Boston, Massachusetts

May 10, 2023

EIP Pharma, Inc.

Balance Sheets

	December 31,	
	2022	2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,093,579	\$ 6,666,338
Prepaid expenses and other current assets	64,127	149,231
TOTAL ASSETS	\$ 4,157,706	\$ 6,815,569
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	\$ 97,302	\$ 18,148
Accrued expenses and other current liabilities	644,252	428,573
Convertible debt, current	12,414,000	4,110,000
TOTAL CURRENT LIABILITIES	13,155,554	4,556,721
LONG TERM LIABILITIES:		
Convertible debt	\$ -	\$ 5,915,000
TOTAL LIABILITIES	13,155,554	10,471,721
Commitments and Contingences (Note 10)		
CONVERTIBLE PREFERRED STOCK		
Series A-1 preferred stock \$0.001 par value; Authorized - 17,033,883 shares; Issued and outstanding - 17,033,883 shares at December 31, 2022 and 2021; aggregate liquidation preference of \$1,516,015 at December 31, 2022	246,849	246,849
Series A-2 preferred stock, \$0.001 par value; Authorized - 2,916,686 shares; Issued and outstanding - 2,916,686 shares at December 31, 2022 and 2021; aggregate liquidation preference of \$4,200,000 at December 31, 2022	4,173,267	4,173,267
Series B preferred stock, \$0.001 par value; Authorized - 8,991,228 shares; Issued and outstanding - 8,991,228 shares at December 31, 2022 and 2021; aggregate liquidation preference of \$20,500,000 at December 31, 2022	19,867,095	19,867,095
TOTAL CONVERTIBLE PREFERRED STOCK	24,287,211	24,287,211
STOCKHOLDERS' DEFICIT		
Common stock \$0.001 par value; Authorized - 36,000,000 shares; Issued and outstanding - 4,501,652 shares at December 31, 2022 and 2021	4,502	4,502
Additional paid-in capital	18,979,355	18,518,004
Accumulated deficit	(52,268,916)	(46,465,869)
Total stockholders' deficit	(33,285,059)	(27,943,363)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT	\$ 4,157,706	\$ 6,815,569

The accompanying notes are an integral part of these financial statements.

EIP Pharma, Inc.

Statements of Operations

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	1,336,469	\$ 2,421,593
General and administrative	2,139,065	2,615,520
Total operating expenses	3,475,534	5,037,113
Loss from operations	(3,475,534)	(5,037,113)
Other income (expense):		
Other income (expense)	(2,389,152)	882,254
Interest income	62,226	19,854
Interest expense	(587)	(429)
Total other income (expense):	(2,327,513)	901,679
Net loss	\$ (5,803,047)	\$ (4,135,434)
Net loss per share, basic and diluted	\$ (1.29)	\$ (0.92)
Weighted average common shares outstanding, basic and diluted	4,501,652	4,501,652

The accompanying notes are an integral part of these financial statements.

EIP Pharma, Inc.

Statement of Changes in Convertible Preferred Stock and Stockholders' Deficit

	Preferred Series A-1		Preferred Series A-2		Preferred Series B		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Deficit
Balance as of December 31, 2020	<u>17,033,883</u>	<u>\$ 246,849</u>	<u>2,916,686</u>	<u>\$4,173,267</u>	<u>8,991,228</u>	<u>\$19,867,095</u>	<u>4,501,652</u>	<u>\$ 4,502</u>	<u>\$17,474,908</u>	<u>\$ (42,330,435)</u>	<u>\$ (24,851,025)</u>
Stock-based compensation expense	-	-	-	-	-	-	-	-	666,896	-	666,896
Contributed capital in lieu of executive compensation	-	-	-	-	-	-	-	-	291,200	-	291,200
Issuance of convertible debt	-	-	-	-	-	-	-	-	85,000	-	85,000
Net loss	-	-	-	-	-	-	-	-	-	(4,135,434)	(4,135,434)
Balance as of December 31, 2021	<u>17,033,883</u>	<u>\$ 246,849</u>	<u>2,916,686</u>	<u>\$4,173,267</u>	<u>8,991,228</u>	<u>\$19,867,095</u>	<u>4,501,652</u>	<u>\$ 4,502</u>	<u>\$18,518,004</u>	<u>\$ (46,465,869)</u>	<u>\$ (27,943,363)</u>
Stock-based compensation expense	-	-	-	-	-	-	-	-	333,835	-	333,835
Contributed capital in lieu of executive compensation	-	-	-	-	-	-	-	-	127,516	-	127,516
Net loss	-	-	-	-	-	-	-	-	-	(5,803,047)	(5,803,047)
Balance as of December 31, 2022	<u>17,033,883</u>	<u>\$ 246,849</u>	<u>2,916,686</u>	<u>\$4,173,267</u>	<u>8,991,228</u>	<u>\$19,867,095</u>	<u>4,501,652</u>	<u>\$ 4,502</u>	<u>\$18,979,355</u>	<u>\$ (52,268,916)</u>	<u>\$ (33,285,059)</u>

The accompanying notes are an integral part of these financial statements

EIP Pharma, Inc.

Statements of Cash Flows

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (5,803,047)	\$ (4,135,434)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	333,835	666,896
Contributed capital in lieu of executive compensation	127,516	291,200
Loan forgiveness income	-	(147,254)
Interest income	-	(19,479)
Change in fair value of convertible debt	2,389,000	(735,000)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	85,104	554,826
Increase (decrease) in:		
Accounts payable	79,154	(150,682)
Accrued expenses and other current liabilities	215,679	(459,608)
Net cash used in operating activities	<u>(2,572,759)</u>	<u>(4,134,535)</u>
Cash flows from financing activities:		
Stock subscription payable	-	-
Net proceeds from issuance of convertible debt	-	6,000,000
Net cash provided by financing activities	<u>-</u>	<u>6,000,000</u>
Net increase (decrease) in cash and cash equivalents	(2,572,759)	1,865,465
Cash and cash equivalents, beginning of period	6,666,338	4,800,873
Cash and cash equivalents, end of period	<u>\$ 4,093,579</u>	<u>\$ 6,666,338</u>

The accompanying notes are an integral part of these financial statements

EIP Pharma, Inc.**Notes to Financial Statements****1. The Company and Liquidity**

EIP Pharma, Inc. (the “Company”) is a corporation organized under the laws of the state of Delaware and headquartered in Boston, Massachusetts. The Company is a clinical stage therapeutics company dedicated to the development and commercialization of drug treatments for neurodegenerative diseases with a focus on the early stages of the neurodegenerative process.

To date, the Company has devoted substantially all of its efforts to product research and development and raising capital. The Company has operated at a loss since its inception and has no recurring revenue from operations. Further, the Company is subject to a number of risks similar to those of other life science companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the industry, including rapid technological change, regulatory approval of products, uncertainty of market acceptance of products, compliance with government regulations, protection of proprietary technology, dependence on third parties, and product liability. The Company expects to continue to incur significant expenses and operating losses for at least the next several years.

Liquidity and Capital Resources

The Company has incurred net operating losses since inception and has generated negative cash flows from operations. As of December 31, 2022 and 2021, the Company had accumulated deficit of approximately \$52.3 million and \$46.5 million, respectively. In January 2023, the Company was awarded a \$21.0 million grant from the National Institute of Aging (NIA) to support a Phase 2b study of neflamapimod in dementia with Lewy bodies. This is expected to be received over a three-year period. However currently, the Company’s convertible debt totaling \$12.4 million becomes due December 2023. Management believes that, without additional debt or equity financing or extension of its convertible notes, its existing cash resources will not be sufficient to fund its current operating plan and meet its obligations as they become due for a period of at least one year from the date of the issuance of these financial statements. In the future, the Company may raise additional capital through a variety of sources, including public or private equity offerings, debt financings, grant funding, or strategic collaborations and licensing arrangements. Adequate additional financing may not be available on acceptable terms, or at all. The Company’s failure to raise capital would have a negative effect on its financial condition and its ability to pursue the Company’s business strategy. If the Company is unable to secure additional capital in sufficient amounts or on acceptable terms, the Company may have to delay, scale back or discontinue its development or commercialization activities for drug treatments. The Company might also be required to seek funds through arrangements with third parties that require the Company to relinquish certain of its rights to intellectual property or otherwise agree to unfavorable terms. Based on these factors, management has concluded that substantial doubt exists about the Company’s ability to continue as a going concern for a period of at least twelve months from the date of the financial statements.

2. Summary of Significant Accounting Policies***Basis of Presentation***

The financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“GAAP”) as defined by the Financial Accounting Standards Board (“FASB”).

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, and related disclosures. On an ongoing basis, the Company's management evaluates its estimates, including estimates related to money market accounts, clinical trial accruals, convertible notes, stock-based compensation expense, and reported amounts of expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalent balances with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance-sheet risk of loss. The Company has not experienced any losses in such accounts.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value. There are no unrealized gains or losses on the money market funds for the periods presented.

Fair Value of Financial Instruments

The Company's financial instruments consists primarily of cash, accounts payable, convertible notes and accrued liabilities. The Company's cash, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. The Company determined the fair value of the convertible notes as described in Note 9.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Leases

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016 02, “Leases” (“ASC 842”), which establishes a right-of-use model (“ROU”) that requires a lessee to recognize an ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement as well as the reduction of the right-of-use asset. The new standard provides a number of optional practical expedients in transition. The Company has elected to apply (i) the practical expedient, which allows us to not separate lease and non-lease components, for new leases and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the new standard. The Company adopted ASC 842 on January 1, 2021.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company’s control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

The Company has elected to combine lease and non-lease components as a single component. Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances, while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis. The adoption of ASC 842 did not have a material impact on the Company’s financial statements.

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of new product development. Research and development costs include salaries and benefits, consultants’ fees, process development costs and stock-based compensation, as well as fees paid to third parties that conduct certain research and development activities on the Company’s behalf.

A substantial portion of the Company’s ongoing research and development activities are conducted by third-party service providers. The Company records accrued expenses for estimated preclinical study and clinical trial expenses. Estimates are based on the services performed pursuant to contracts with research institutions, contract research organizations in connection with clinical studies, investigative sites in connection with clinical studies, vendors in connection with preclinical development activities, and contract manufacturing organizations in connection with the production of materials for clinical trials. Further, the Company accrues expenses related to clinical trials based on the level of subject enrollment and activity according to the related agreement. The Company monitors subject enrollment levels and related activity to the extent reasonably possible and make judgments and estimates in determining the accrued balance in each reporting period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development.

If the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from estimates. To date, the Company has not experienced significant changes in its estimates of preclinical studies and clinical trial accruals.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-based Compensation

Stock-based compensation for employee and non-employee awards is measured on the grant date based on the fair value of the award and recognized on a straight-line basis over the requisite service period. The fair value of stock options to purchase common stock are measured using the Black-Scholes option pricing model. The Company accounts for forfeitures as they occur.

The fair value of stock options is determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. The Company uses the “simplified method” to estimate the expected term of stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the Company stock options, taking into consideration multiple vesting tranches. The Company utilizes this method due to lack of historical data and the plain-vanilla nature of the Company’s share-based awards.

Expected Volatility—The Company has limited information on the volatility of common stock as the shares are not actively traded on any public markets. The expected volatility was derived from the historical stock volatilities of comparable peer public companies within its industry. These companies are considered to be comparable to the Company’s business over a period equivalent to the expected term of the stock-based awards.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the and stock options expected term.

Expected Dividend Rate—The expected dividend is zero as the Company has not paid, nor does it anticipate paying, any dividends on its stock options in the foreseeable future.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to recover or settle. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income for the period that includes the enactment date.

The deferred tax assets are recognized to the extent the Company believes that these assets are more likely than not to be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company’s historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company records uncertain tax positions using a two-step process. First, the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position. Second, for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits on the interest expense line and other expense line, respectively, in the accompanying statements of operations. Accrued interest and penalties are included on the related liability lines in the balance sheet.

Net Loss Per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per common share after giving consideration to all potentially dilutive common shares, including options and warrants to purchase common stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and basic and diluted loss per share have been the same.

Segments

The Company has one operating segment. The Company's chief decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for purposes of allocating resources.

Recent Accounting Pronouncements

In January 2021, the FASB issued ASU No. 2021-01 "Reference Rate Reform (Topic 848): Scope" ("ASU 2021-01"), which permits entities to elect certain optional expedients and exceptions when accounting for derivatives and certain hedging relationships affected by changes in interest rates and the transition. The Company is evaluating the potential impact of the replacement of LIBOR from both a risk management and financial reporting perspective. The Company's current portfolio of debt and financial instruments tied to LIBOR consists primarily of a line of credit in the amount of \$2,500,000, for which there was no drawdown as of December 31, 2022. The Company does not currently believe that this transition will have a material impact on its financial statements.

In August 2020, the FASB issued ASU No. 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)" ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. The ASU's amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company elected to early adopt ASU 2020-06 during the year ended December 31, 2022 using the modified retrospective method, which did not have a material impact on the financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"), together with a series of subsequently issued related ASUs, has been codified in Topic 326. Topic 326 establishes new requirements for companies to estimate expected credit losses when measuring certain financial assets, including accounts receivables. The new guidance is effective for fiscal years beginning after December 15, 2022. The Company is currently evaluating the effect that the new guidance will have on its financial statements and related disclosures.

3. Significant Agreements and Contracts

In August 2012, the Company entered into an option and license agreement (“Agreement”) for an option to acquire an exclusive license to develop and commercialize a drug candidate “VX-745” from Vertex Pharmaceuticals Inc. (“Vertex”). The Agreement required the Company to pay a nonrefundable upfront license fee upon exercising the option to license VX-745 and downstream milestones and royalties upon achieving certain development, regulatory and revenue milestones as discussed further below. The Agreement gave the Company an option with Vertex on VX-745 for the exclusive worldwide use in the field of diagnosis, treatment and prevention of Alzheimer’s disease and related central nervous system disorders in humans.

The Agreement was amended by the Company in April 2014 to change the amount of the option fee and downstream milestones and royalties. In August 2014, the Company exercised its option and paid an option fee of \$100,000, which was expensed as incurred. In November 2015, the Agreement was further amended for additional changes to downstream milestones and royalties.

The Company is obligated to make certain payments totaling up to approximately \$134.5 million upon achievement of certain regulatory and sales milestones, and royalties on net sales of products and indications covered by the agreement. The Company has made a total of \$100,000 in payments to the Vertex since inception. As of December 31, 2022, none of the future milestones or downstream royalties have been reached.

4. Fair Value Measurements

The following table summarizes the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicated the level of the fair value hierarchy utilized to determine such fair values.

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	\$ 3,719,348	\$ -	\$ -	\$ 3,719,348
Total financial assets	<u>\$ 3,719,348</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,719,348</u>
Liabilities:				
Convertible notes	\$ -	\$ -	\$ 12,414,000	\$ 12,414,000
Total financial liabilities	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 12,414,000</u>	<u>\$ 12,414,000</u>
December 31, 2021				
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	\$ 6,207,216	\$ -	\$ -	\$ 6,207,216
Total financial assets	<u>\$ 6,207,216</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 6,207,216</u>
Liabilities:				
Convertible notes	\$ -	\$ -	\$ 10,025,000	\$ 10,025,000
Total financial liabilities	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 10,025,000</u>	<u>\$ 10,025,000</u>

The following table presents a roll-forward of the fair value of the convertible note for which fair value is determined by Level 3 inputs:

	<u>Convertible Note</u>
Balance January 1, 2021	\$ 4,845,000
Issuance of convertible notes	5,915,000
Fair market adjustments	(735,000)
Balance December 31, 2021	\$ 10,025,000
Fair market adjustments	2,389,000
Balance December 31, 2022	<u>\$ 12,414,000</u>

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs (See Note 9). Our convertible notes are classified within Level 3 of the fair value hierarchy because the fair value measurement is based, in part, on significant inputs not observed in the market.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2022 or 2021.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at December 31, 2022 and 2021 consisted of the following:

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Receivables due from contract research organizations	\$ -	\$ 69,581
Insurance	9,937	17,987
Rent	2,455	5,800
Prepaid clinical expenses	-	920
Other	51,735	54,943
Total prepaid and other current assets	<u>\$ 64,127</u>	<u>\$ 149,231</u>

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities at December 31, 2022 and 2021 consisted of the following:

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Employee compensation costs	\$ 364,070	\$ 204,278
Professional fees	206,675	192,395
Clinical development costs	23,185	-
Other	50,322	31,900
Total accrued expenses and other current liabilities	<u>\$ 644,252</u>	<u>\$ 428,573</u>

7. Line of Credit

The Company established a line of credit with a lender during 2020 in the amount of \$2,500,000, with a variable interest rate of 1.75% over the 30-day LIBOR (6.08% and 1.85% at December 31, 2022 and 2021, respectively). The line was secured by the personal assets of the Company's Chief Executive Officer and Executive Chair of the Board.

No drawdowns were made, and no costs incurred related to the line of credit during the years ended December 31, 2022 or 2021.

8. Paycheck Protection Program ("PPP") Loan

On April 19, 2020, the Company received loan proceeds in the amount of \$145,800 under the Paycheck Protection Program. The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after eight weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the eight-week period.

During 2021 the Company was informed by its lender that the Small Business Administration had completed its review of the Company's Paycheck Protection Program forgiveness application and all principal and interest of 1% under the loan had been remitted, and therefore, forgiven in full which is reflected in other income in the year ended December 31, 2021.

9. Convertible Note Payable

In December 2020, the Company issued convertible notes, hereafter the 2020 Notes, to predominantly related party investors for proceeds of \$5,078,500. Upon issuance, the Company elected the fair value option for the 2020 Notes in accordance with ASC 825, "Financial Instruments," pursuant to which the entire instrument, including interest expense, is measured at fair value with the initial change in fair value deemed to be a capital contribution and any subsequent changes in fair value being recorded to other income (expense). The fair value of the 2020 Notes as of December 31, 2022 and 2021 was determined to be \$6,484,000 and \$4,110,000, respectively. The fair value adjustments of (\$2,374,000) and \$735,000 were recognized in other income (expense) at December 31, 2022 and 2021, respectively.

In December 2021, the Company issued convertible notes, hereafter the 2021 Notes, to predominantly related party investors for proceeds of \$6,000,000. Upon issuance, the Company elected the fair value option for the 2021 Notes, with the initial change in fair value deemed to be a capital contribution and any subsequent changes in fair value being recorded to other income (expense). The fair value of the 2021 Notes as of December 31, 2022 and 2021 was determined to be \$5,930,000 and \$5,915,000, respectively. The fair value adjustment of \$15,000 was recognized in other income (expense) at December 31, 2022, while the calculated adjustment in fair value of \$85,000 was recorded to additional paid-in capital at issuance as a capital contribution at December 31, 2021.

In April 2022, the Company entered into an amendment with the noteholders for the 2020 Notes (the "Amendment"). In accordance with the Amendment, the maturity of the 2020 Notes was extended from June 2022 to December 2023, the interest rate was modified so interest accrued at 5% through the original maturity of June 2022 and at 0% thereafter, the conversion discount was increased from 20% to 30%, and a conversion price limit of \$3.00 was established, as discussed further below. Expenses associated with the amendment were de minimis.

The Company concluded the Amendment qualified as a troubled debt restructuring, in accordance with FASB ASC 470, *Debt*, as the noteholders for the 2020 Notes, for economic reasons related to the Company's financial difficulties, granted concessions to the Company. The Company concluded no gain or loss, and no adjustment to, or reclassification of, the carrying value of the 2020 Notes were considered necessary as a result of the Amendment. In addition, the Company concluded there was no other financial statement impact as a result of the Amendment, as any prospective change would be related to interest and, as a result of the amendment, the interest rate decreased to 0% following the original maturity of June 2022.

The 2020 Notes accrued interest at an annual rate of 5% through June 2022 and, following the Amendment, 0% thereafter. The 2020 Notes, which had an original maturity date of June 2022, have a maturity date of December 2023 following the Amendment. The 2021 Notes do not accrue any interest and have a maturity date of December 2023. No payments of principal or interest are due prior to maturity.

Subsequent to the Amendment, the terms of the 2020 Notes and the 2021 Notes provide for automatic conversion upon either (i) the occurrence of a qualified financing of at least \$15,000,000 in gross proceeds, in which the outstanding principal and all accrued and unpaid interest shall convert into shares of the equity financing at a conversion price equal to the lesser of 70% of the price per share or \$3.00 per share; (ii) the occurrence of an initial public offering, in which the outstanding principal and all accrued and unpaid interest shall convert into common shares offered in the initial public offering at a conversion price equal to the initial public offering price; or (iii) the occurrence of special purpose acquisition company ("SPAC") transaction or a Reverse Merger, in which the outstanding principal and all accrued and unpaid interest shall convert into common shares determined in connection with and at the time of the SPAC transaction, or Reverse Merger, at the conversion price. The terms of the 2020 Notes and the 2021 Notes further provide the holders an option to convert in connection with a financing transaction that is not a qualified financing in which the outstanding principal and all accrued and unpaid interest shall convert into shares of the equity financing at a conversion price equal to the lesser of 70% of the price per share or \$3.00 per share for the 2020 Notes and the 2021 Notes.

The terms of the 2020 Notes and the 2021 Notes further provide for payment of 150% of all outstanding principal and all accrued and unpaid interest in the event of a change in control of the Company. The 2021 Notes also have the option to fully convert to common stock at a price per share equal to the conversion price in the event of a change in control.

The fair value of the 2020 Notes and the 2021 Notes as of December 31, 2022, and the fair value of the 2021 Notes as of December 31, 2021, were estimated as the combination of a zero-coupon bond and a call option. The combined values for each of the 2020 Notes and the 2021 Notes as of December 31, 2022 were then weighted by the probability of completing a financing or reverse merger, while the combined value for the 2021 Notes as of December 31, 2021 was then weighted by the probability of completing a financing. This approach resulted in the classification of the 2020 Notes as of December 31, 2022, and the 2021 Notes as of December 31, 2022 and 2021, as Level 3 of the fair value hierarchy (Note 4). The assumptions utilized to value the 2020 Notes and the 2021 Notes as of December 31, 2022 were an estimated term of 0.94 years, volatility of 80.0% and a market yield of 55.2%. The assumptions utilized to value the 2021 Notes as of December 31, 2021 were an estimated term of 1.94 years, volatility of 81.0% and a market yield of 45.2%. The measurement of fair value incorporates expected future cash flows associated with interest payments; as such, there is no separate accrual for interest accrued but not yet paid.

The fair value of the 2020 Notes as of December 31, 2021 was estimated using a yield method, with inputs based on certain subjective assumptions, including principally estimated term and implied debt yields. This approach resulted in the classification of the 2020 Notes as of December 31, 2021 as Level 3 of the fair value hierarchy (Note 4). The assumptions utilized to value the 2020 Notes were an estimated term of 1.50 years and an implied yield of 45.2%. As a result of the Amendment to the terms of the 2020 Notes, the Company changed from using this fair value methodology in order to align with the valuation assumptions and methodology applied for the 2021 Notes at December 31, 2022 as the amendment updated the terms of the 2020 Notes to align with the 2021 Notes.

10. Commitments and Contingencies

Operating Lease

Effective September 2022, the Company entered into a six month lease for its office space in Boston, Massachusetts, which allowed for automatic extensions until a 90 notice is rendered to the lessor from the Company. Under the terms of the lease, lease payments are \$2,800 per month and are recognized as incurred. As the term of this lease is less than 12 months it meets the short-term lease exemption under ASC 842.

During 2021, the Company was party to a lease for office space in Boston Massachusetts that expired in August 2021. Under the terms of the lease, lease payments were \$4,340 per month and were recognized as incurred.

Lease costs for the years ended December 31, 2022 and 2021, were \$44,664 and \$58,210, respectively.

Contingencies

From time to time, the Company may be involved in disputes or regulatory inquiries that arise in the ordinary course of business. When the Company determines that a loss is both probable and reasonably estimable, a liability is recorded and disclosed if the amount is material to the financial statements taken as a whole. When a material loss contingency is only reasonably possible, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can reasonably be made.

As of December 31, 2022 and 2021, there was no litigation or contingency with at least a reasonable possibility of a material loss.

11. Common Stock

The voting, dividend and liquidation rights of the holders of common stock are subject to the rights, powers and preferences of the holders of preferred stock. Common stockholders are entitled to one vote per share, and to receive dividends, when and if declared by the Company's Board of Directors (the "Board").

There were 36,000,000 shares authorized and 4,501,652 shares of common stock outstanding at December 31, 2022 and 2021.

As of December 31, 2022 and 2021, the Company has warrants outstanding to purchase an aggregate of 378,982 shares of common stock with an exercise price of \$2.28 per share. The warrants have an expiration date of April 2, 2028. The Company evaluated the accounting classification of the warrants and concluded that they should be accounted for as equity. As of the date of these financial statements, the warrants associated with Series B Preferred Stock financing remain outstanding and have not been exercised.

12. Preferred Stock

The following table summarizes the authorized and the issued and outstanding preferred stock of the Company:

	December 31, 2022			
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Aggregate Liquidation Preference
Preferred Stock:				
Series A-1	17,033,883	17,033,883	\$ 0.089	\$ 1,516,015
Series A-2	2,916,686	2,916,686	\$ 1.440	4,200,000
Series B	8,991,228	8,991,228	\$ 2.280	20,500,000
Total preferred stock	28,941,797	28,941,797		\$ 26,216,015

The Company recorded its preferred stock at the issuance price on the dates of issuance, net of issuance costs. As of December 31, 2022 and 2021, the Company classified the preferred stock as temporary equity because the shares are contingently redeemable outside the control of the Company. During the years ended December 31, 2022 and 2021, the Company did not adjust the carrying values of the preferred stock to the deemed redemption values of such shares since a redemption event was not probable of occurring. Subsequent adjustments to increase the carrying values to the ultimate redemption values will be made only when it becomes probable that such a redemption event will occur.

As of December 31, 2022, the holders of the preferred stock had the following rights and preferences.

Voting Rights

Each holder of outstanding shares of preferred stock shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of preferred stock held by the holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Holders of preferred stock shall vote together with holders of common stock as a single class. The holders of Series A-1 Preferred Stock and Series A-2 Preferred Stock, as a separate class, shall be entitled to elect one member of the Company's Board of Directors as long as they continue to own beneficially 10,000,000 shares of Series A-1 Preferred Stock and Series A-2 Preferred Stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to Series A-1 Preferred Stock and Series A-2 Preferred Stock. The holders of Series B Preferred stock, as a separate class, shall be entitled to elect one member of the Company's Board of Directors as long as they continue to own beneficially 4,500,000 shares of Series B Preferred stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to Series B Preferred stock. The holders of common stock and any other class or series of voting stock, including Series A-1 Preferred Stock and Series A-2 Preferred Stock and Series B Preferred Stock, voting together as a single class shall be entitled to elect the balance of the total number of directors of the Company.

Additionally, as long as at least 1,000 shares of Preferred Stock are outstanding (subject to adjustment in the event of any recapitalizations), the Company must obtain approval from holders of at least a majority of the outstanding shares of Preferred Stock (the "Requisite Preferred Holders") in order to effect certain corporate actions.

Dividend Rights

The Company's preferred stock does not have a stated dividend rate. The Company shall not declare, pay or set aside any dividend on shares of any class or series of capital stock of the Company unless the holders of the preferred stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of preferred stock in an amount at least equal to (i) in the case of a dividend on common stock or any class or series that is convertible into common stock, that dividend per share of preferred stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of a share of preferred stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of preferred stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the applicable Original Issue Price (as defined below); provided that, if the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of preferred stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest preferred stock dividend.

The Original Issue Price of each series of preferred stock shall be as follows: (i) with respect to the Series A-1 Preferred Stock, Original Issue Price shall mean \$0.089 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A-1 Preferred Stock; (ii) with respect to the Series A-2 Preferred Stock, the Original Issue Price shall mean \$1.44 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A-2 Preferred Stock; and (iii) with respect to the Series B Preferred Stock, Original Issue Price shall mean \$2.28 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or Deemed Liquidation Event (as defined below), the holders of preferred stock shall be entitled to receive, before any payments of the Company to the holders of shares of common stock, the greater of (i) an amount equal to the Original Issuance Price per share for each series of preferred stock, plus all declared and unpaid dividends on such shares or (ii) such amount per share as would have been payable had all shares of such applicable series of preferred stock been converted to common stock immediately prior to such liquidation event. If available assets are insufficient to pay the full liquidation preference, available assets will be distributed ratably among the holders of the preferred stock based on amounts that would be received if such shares were paid in full. After the payment of the liquidation preference, all remaining assets available for distribution will be distributed ratably among the holders of the common stock.

A Deemed Liquidation Event is defined as (i) a merger or consolidation in which the Company or a subsidiary of the Company is a constituent party and the Company issues shares of its common stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Company or a subsidiary in which the shares of common stock of the Company outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of common stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the common stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or (ii) a sale, lease, transfer exclusive license, or other disposition in a single transaction or series of related transactions of all or substantially all of the assets of the Company unless the Requisite Preferred Holders elect otherwise by written notice sent to the Company at least ten days prior to the effective date of any such event.

Optional Conversion Rights

Each share of preferred stock is, at the option of the holder, convertible into the number of fully paid and non-assessable shares of common stock as determined by dividing the Original Issue Price applicable to such preferred stock by the conversion price in effect at that time. The conversion price for each series of convertible preferred stock shall initially be the Original Issue Price of such series of preferred stock and is subject to adjustment from time to time for events such as future stock splits, combinations, and dividends in accordance with conversion provisions contained in the Company's Amended and Restated Certificate of Incorporation.

Mandatory Conversion Rights

Each share of preferred stock is automatically convertible into shares of common stock-based on the then effective conversion price upon either (a) the closing of a sale of common stock to the public at a price of \$6.84 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalizations with respect to common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$50 million of gross proceeds to the Company or (b) the occurrence of an event, specified by the Requisite Preferred Holders, then all outstanding shares of preferred stock shall automatically be converted into shares of common stock, at the effective conversion rate for the Series A-1 Preferred Stock, the Series A-2 Preferred Stock, and the Series B Preferred Stock.

13. Stock-Based Compensation Expense*2018 Stock Option and Grant Plan*

On March 28, 2018, the Company adopted the 2018 EIP Pharma, Inc. Employee, Director and Consultant Equity Incentive Plan (the "2018 Plan") under which the Company may issue incentive stock options, non-qualified stock options, stock grants, and other stock-based awards to employees, directors, and consultants, as specified in the 2018 Plan. The Board of Directors has the authority to determine to whom options or stock will be granted, the number of shares, the term, and the exercise price. Options granted under the 2018 Plan have a term of up to ten years and generally vest over a four-year period with 25% of the options vesting after one-year of service and the remainder vesting monthly thereafter. As of December 31, 2022, the Company had reserved 1,435,000 shares of common stock for issuance under the 2018 Plan, of which 440,000 shares were available for issuance.

Activity for the options to purchase common stock shown below:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	1,136,000	\$ 2.88	8.29	1,289,390
Granted	327,000	\$ 4.01		
Cancelled	(270,750)	\$ 3.42		
Outstanding as of December 31, 2021	1,192,250	\$ 3.05	6.26	1,130,876
Granted	40,000	\$ 2.24		
Cancelled	(237,250)	\$ 3.22		
Outstanding as of December 31, 2022	995,000	\$ 2.87	6.72	-
Exercisable as of December 31, 2022	768,447	\$ 2.85	6.34	\$ -

As of December 31, 2022, total unrecognized stock-based compensation related to unvested stock options issued was \$474,304, which the Company expects to recognize over a remaining weighted-average period of 2.12 years. The Company records forfeitures as they occur.

The Company recognized stock-based compensation expense for stock options as follows:

	December 31,	
	2022	2021
Research and development	\$ 174,710	\$ 181,427
General and administrative	159,124	485,469
Total stock-based compensation expense	<u>\$ 333,835</u>	<u>\$ 666,897</u>

Determination of Fair Value

The estimated grant-date fair value of all the Company's options to purchase common stock was calculated using the Black-Scholes option pricing model, based on the following assumptions:

	December 31,	
	2022	2021
Expected term (in years)	6.0	6.0
Expected volatility	80.3%	81.0%-82.0%
Risk-free interest rate	1.9%	1.0%
Dividend yield	0%	0%

Contributed capital in lieu of Executive Compensation

In 2022 and 2021 the Executive Chair of the Board and the Chief Executive Officer offered to forego, without repayment, certain compensation to ensure the Company had enough resources to maintain operations until the financial funding is completed. These amounts of \$127,516 and \$291,200 for the years ended December 31, 2022 and 2021, respectively, which is recorded as contributed capital in additional paid-in capital, will not be paid in cash, debt or equity in the future.

14. Net Loss Per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per share of common stock after giving consideration to all potentially dilutive shares of common stock, including options to purchase common stock and warrants to purchase common stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential shares of common stock have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

The following table sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	\$ (5,803,047)	\$ (4,135,434)
Denominator:		
Weighted average common stock outstanding, basic and diluted	4,501,652	4,501,652
Net loss per share, basic and diluted	<u>\$ (1.29)</u>	<u>\$ (0.92)</u>

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive:

	Year Ended December 31,	
	2022	2021
Preferred Series A-1	17,033,883	17,033,883
Preferred Series A-2	2,916,686	2,916,686
Preferred Series B	8,991,228	8,991,228
Warrants	378,982	378,982
Stock Options	995,000	1,192,250
Total	<u>30,315,779</u>	<u>30,513,029</u>

15. Income Taxes

The Company is classified as a C-Corporation for U.S. income tax purposes. The Company incurred net losses for the years ended December 31, 2022 and 2021. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets.

The tax effects of temporary differences that give rise to significant components of the Company's deferred tax assets as of December 31, 2022 and 2021, consist of:

	2022	2021
Deferred tax assets:		
Net operating loss	\$ 10,977,455	\$ 10,417,336
Research and development credits	354,283	282,855
Capitalized research expenditures	259,749	-
Stock-based compensation	514,654	428,932
Reserves and accruals	105,399	139,053
Intangibles	262,872	288,119
Gross deferred tax assets	12,474,412	11,556,295
Less valuation allowance	(12,474,412)	(11,556,295)
Total deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Evaluating the need for a valuation allowance for deferred tax assets often requires judgment and analysis of all the positive and negative evidence available, including cumulative losses in recent years and projected future taxable income, to determine whether all or some portion of the deferred tax assets will not be realized. As of December 31, 2022, the Company has utilized a full valuation allowance to offset the net deferred tax assets as the Company believes it is not more likely than not that the net deferred tax assets will be fully realizable. The valuation allowance increased by \$918,117 during the year ended December 31, 2022.

As of December 31, 2022, the Company had net operating loss ("NOL") carryforwards of approximately \$38,181,260 and \$37,230,123 for federal and state tax purposes, respectively. Federal NOL carryforwards will not expire and state NOL carryforwards will begin to expire in 2038, if not utilized. The Tax Cuts and Jobs Act (TCJA) enacted on December 22, 2017 limits a taxpayer's ability to utilize NOL deduction in a year to 80% taxable income for federal net operating losses arising in tax years beginning after 2017.

As of December 31, 2022, the Company also had federal and state research credit carryforwards of \$232,293 and \$121,989, respectively. The federal and state research credits will begin to expire in 2038 and 2034, respectively.

Generally, utilization of the NOL carryforwards and credits may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Code, which provides for limitations on NOL carryforwards and certain built-in losses following ownership changes, and Section 383 of the Code, which provides for special limitations on certain excess credits, as well as similar state provisions. Accordingly, the Company's ability to utilize NOL carryforwards may be limited as the result of such an "ownership change." A formal Section 382 study was not performed through December 31, 2022 the NOL carryforwards could be subject to an annual limitation, resulting in a reduction in the gross deferred tax assets before considering the valuation allowance. Further, a portion of the NOL carryforwards may expire before being applied to reduce future earnings.

The Company files federal and state income tax returns in jurisdictions with varying statutes of limitations. Due to its NOL carryforwards, the Company's income tax returns generally remain subject to examination by federal and state tax authorities. The Company is currently not subject to any income tax audits by federal or state taxing authorities. The statute of limitations for tax liabilities for all years remains open.

The Company uses the "more likely than not" criterion for recognizing the income tax benefit of uncertain income tax positions and establishing measurement criteria for income tax benefits. The Company has evaluated the impact of these positions and believes that its income tax filing positions and deductions will be sustained upon examination. Accordingly, no reserves for uncertain income tax positions or related accruals for interest and penalties have been recorded as of December 31, 2022 and 2021.

16. Employee 401(k) Plan

The Company has a qualified contributory savings plan under Section 401(k) of the Internal Revenue Code (the "Code") covering substantially all of the Company's U.S. employees. The Company's 401(k) plan is designed to provide tax-deferred retirement benefits in accordance with the provisions of Section 401(k) of the Code. Eligible employees may defer up to 100% of their eligible compensation up to the annual maximum as determined by the Internal Revenue Service. The Company's contributions to the plan are discretionary. For the years ended December 31, 2022 and 2021, the Company did not make any contributions to the plan.

17. Subsequent Events

The Company has evaluated subsequent events that may require adjustments to or disclosure in the financial statements through April xx, 2023, the date on which the December 31, 2022 financial statements were issued.

National Institute of Aging (NIA) Grant

In January 2023, the Company was awarded a \$21.0 million grant from the NIA to support a Phase 2b study of neflamapimod in dementia with Lewy bodies. The grant monies are received over a period of three years including \$6.7 million in 2023, \$8.1 million in 2024 and \$6.2 million in 2025.

Banking

On March 10, 2023, Silicon Valley Bank (“SVB”), based in Santa Clara, California, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. At the time of closing, the Company had no deposit accounts at SVB. The Company continues to monitor the circumstances surrounding SVB. The Company does not anticipate a material impact on its financial condition or operations.

Merger

On March 30, 2023, the Company entered into a definitive merger agreement (the “Merger Agreement”) by and among Diffusion Pharmaceuticals Inc. (“Diffusion”), Dawn Merger Sub Inc. a Delaware corporation and wholly owned Subsidiary of Diffusion (“Merger Sub”) and the Company. The Merger Agreement is subject to the satisfaction or waiver of certain closing conditions. Diffusion and the Company intend to effect a merger of Merger Sub with and into the Company (the “Merger”) in accordance with the Merger Agreement and the General Corporation Law of the State of Delaware (the “DGCL”), and upon consummation of the Merger, Merger Sub will cease to exist and the Company will become a wholly owned subsidiary of Diffusion.

Immediately after the Merger, the current equity and convertible note holders of the Company are expected to own, in the aggregate, approximately 77.25% of the total number of outstanding shares of common stock of the combined company and the current stockholders of Diffusion are expected to own approximately 22.75%, in each case calculated on a fully diluted and as-converted basis, subject to adjustment as set forth in the Merger Agreement based on, among other things, the amount of Diffusion net cash (as defined in the Merger Agreement) at the closing date.

The combined company is expected to be renamed “CervoMed” and will continue to trade on the Nasdaq Capital Market under a new ticker symbol, CRVO. The Merger Agreement has been approved by the Board of Directors of both companies. The Merger is expected to close in mid-2023, subject to approvals by the Company and Diffusion stockholders, the effectiveness of a registration statement to be filed by Diffusion with the Securities and Exchange Commission to register the shares of Diffusion common stock to be issued to the Company’s security holders in connection with the Merger, and other customary closing conditions.

AGREEMENT AND PLAN OF MERGER

by and among

DIFFUSION PHARMACEUTICALS INC.,

DAWN MERGER SUB INC.,

and

EIP PHARMA, INC.

Dated as of March 30, 2023

THIS FORM OF AGREEMENT SHALL BE KEPT CONFIDENTIAL PURSUANT TO THE TERMS OF THE CONFIDENTIAL DISCLOSURE AGREEMENT ENTERED INTO BY THE RECIPIENT HEREOF (OR ITS AFFILIATE) WITH RESPECT TO THE SUBJECT MATTER HEREOF. THIS FORM OF AGREEMENT IS NOT INTENDED TO CREATE, NOR WILL IT CREATE, A LEGALLY BINDING OR ENFORCEABLE OFFER OR AGREEMENT OF ANY TYPE OR NATURE UNLESS AND UNTIL IT IS EXECUTED AND DELIVERED BY ALL PARTIES. THE PARTIES ACKNOWLEDGE AND AGREE THAT EACH PARTY RESERVES THE RIGHT, IN ITS SOLE DISCRETION, TO REJECT ANY AND ALL PROPOSALS MADE WITH REGARD TO THE POTENTIAL TRANSACTION, AND TO TERMINATE DISCUSSIONS AND NEGOTIATIONS AT ANY TIME, IN SUCH PARTY'S OR ITS AFFILIATES' SOLE AND ABSOLUTE DISCRETION AND WITHOUT GIVING ANY REASON THEREFOR.

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AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER (as it may be amended, restated, supplemented or otherwise modified from to time in accordance with the term hereof, this “Agreement”), dated as of March 30, 2023 by and among Diffusion Pharmaceuticals Inc., a Delaware corporation (“Parent”), Dawn Merger Sub Inc., a Delaware corporation and wholly owned Subsidiary of Parent (“Merger Sub”), and EIP Pharma, Inc., a Delaware corporation (the “Company”). Parent, Merger Sub and the Company are each a “Party” and are collectively referred to herein as the “Parties.”

RECITALS

WHEREAS, Parent and the Company intend to effect a merger of Merger Sub with and into the Company (the “Merger”) in accordance with this Agreement and the General Corporation Law of the State of Delaware (the “DGCL”), and upon consummation of the Merger, Merger Sub will cease to exist and the Company will become a wholly owned subsidiary of Parent;

WHEREAS, the Board of Directors of the Company (the “Company Board”) has unanimously: (a) approved the execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, (b) deemed it fair to, advisable and in the best interests of, the Company and its stockholders to enter into this Agreement, and (c) resolved to recommend adoption of this Agreement by the stockholders of the Company, in each case, in accordance with the General Corporation Law of the State of Delaware (the “DGCL”);

WHEREAS, the respective Boards of Directors of Parent (the “Parent Board”) and Merger Sub (the “Merger Sub Board”) have each unanimously: (a) approved the execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, and, in the case of the Parent Board, the Parent Stockholder Matters, (b) in the case of the Merger Sub Board, deemed it fair to, advisable and in the best interests of, Parent, in its capacity as the sole stockholder of Merger Sub, to enter into this Agreement, and (c) in the case of the Merger Sub Board, resolved to recommend adoption of this Agreement by Parent, in its capacity as the sole stockholder of Merger Sub, in each case, in accordance with the DGCL;

WHEREAS, the Parent Board has resolved to recommend that the holders of shares of common stock, par value \$0.001 per share, of Parent (“Parent Common Stock”) approve the Parent Stockholder Matters and such other actions as contemplated by this Agreement;

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to Parent’s willingness to enter into this Agreement, the officers, directors and stockholders of the Company listed on Section A-1 of the Company Disclosure Letter (solely in their capacity as stockholders of the Company) are executing support agreements in favor of Parent in substantially the form attached hereto as Exhibit A (the “Company Stockholder Support Agreement”), pursuant to which each such Person has, subject to the terms and conditions set forth therein, (i) agreed to vote all of such Person’s shares of Company Capital Stock in favor of the adoption of this Agreement and thereby approve the transactions contemplated by this Agreement, including the Merger, and against any competing proposals and (ii) certified that such Person is an “accredited investor” for the purposes of, and within the meaning of Rule 501(a) of, Regulation D promulgated under the Securities Act;

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Company's willingness to enter into this Agreement, the officers, directors and stockholders of Parent listed on Section A-1 of the Parent Disclosure Letter (solely in their capacity as stockholders of Parent) are executing support agreements in favor of the Company in substantially the form attached hereto as Exhibit B (the "Parent Stockholder Support Agreement"), pursuant to which such Persons have, subject to the terms and conditions set forth therein, agreed to vote all of their shares of Parent Common Stock in favor of the Parent Stockholder Matters;

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to Parent's and the Company's willingness to enter into this Agreement, the Persons listed on Section A-2 of the Company Disclosure Letter and Section A-2 of the Parent Disclosure Letter (solely in their capacity as stockholders) are executing lock-up agreements in favor of Parent in substantially the form attached hereto as Exhibit C (the "Lock-Up Agreements");

WHEREAS, it is expected that within one (1) Business Day after the date of this Agreement, the holders of shares of Company Capital Stock (each of which holders is an Accredited Holder) sufficient to adopt and approve this Agreement and the Merger as required under the DGCL and the Company's Organizational Documents will execute and deliver an action by written consent adopting this Agreement in a form reasonably acceptable to Parent, in order to obtain the Company Stockholder Approval (a "Company Stockholder Written Consent");

WHEREAS, for U.S. federal income Tax purposes, it is intended that the Merger will qualify as a "reorganization" pursuant to Sections 368(a)(1)(A) and 368(a)(2)(E) of the Code and the regulations promulgated thereunder (the "Intended Tax Treatment"), and this Agreement is intended to constitute a "plan of reorganization" within the meaning of the Code; and

WHEREAS, Parent, Merger Sub and the Company each desire to make certain representations, warranties, covenants and agreements in connection with the Merger and also to prescribe certain conditions to the Merger as specified herein.

AGREEMENT

NOW, THEREFORE, in consideration of the premises, and of the representations, warranties, covenants and agreements contained herein, and intending to be legally bound hereby, Parent, Merger Sub and the Company hereby agree as follows:

**ARTICLE I
CERTAIN GOVERNANCE MATTERS**

Section 1.1 Parent Governance Matters.

(a) Parent Certificate of Incorporation. At the Effective Time, the certificate of incorporation of Parent shall be identical to the certificate of incorporation of Parent immediately prior to the Effective Time, until thereafter amended as provided by applicable Law and such certificate of incorporation; provided, however, that at or immediately prior to the Effective Time, Parent shall file an amendment to its certificate of incorporation to (i) change the name of Parent to “CervoMed Inc.”, (ii) effect the Parent Reverse Split (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application), and (iii) make such other changes as shall be mutually agreed upon by Parent and the Company prior to filing such amendment.

(b) Parent Directors and Officers. Unless otherwise agreed by Parent and the Company in writing prior to the Effective Time, the Parties shall take all necessary action to cause: (i) the Parent Board effective as of the Effective Time to be comprised of the individuals as set forth in Section 6.19 and (ii) the individuals as set forth in Section 6.19 to be appointed as the officers of Parent, each to hold office in accordance with the Organizational Documents of Parent until the earlier of his or her death, resignation, disqualification or removal or until their respective successors are duly elected or appointed and qualified.

Section 1.2 Surviving Corporation Governance Matters.

(a) Surviving Corporation Certificate of Incorporation. At the Effective Time, the certificate of incorporation of Merger Sub (as in effect immediately prior to the Effective Time) shall be the certificate of incorporation of Surviving Corporation (except that the name of Surviving Corporation shall be changed to “CervoMed Inc.”), until thereafter amended as provided by such certificate of incorporation or applicable Law.

(b) Surviving Corporation Bylaws. At the Effective Time, the bylaws of Merger Sub (as in effect immediately prior to the Effective Time) shall be the bylaws of Surviving Corporation (except that the name of Surviving Corporation shall be changed to “EIP Pharma, Inc.”), until thereafter amended as provided by such bylaws or applicable Law.

(c) Surviving Corporation Directors and Officers. Unless otherwise agreed by Parent and the Company in writing prior to the Effective Time, the Parties shall take all necessary action to cause: (i) the board of directors of Surviving Corporation effective as of the Effective Time to be comprised of the individuals as set forth in Section 6.19 and (ii) the individuals as set forth in Section 6.19 to be appointed as the officers of Surviving Corporation, each to hold office in accordance with the Organizational Documents of Surviving Corporation until the earlier of his or her death, resignation, disqualification or removal or until their respective successors are duly elected or appointed and qualified.

ARTICLE II THE MERGER

Section 2.1 **Merger.** Upon the terms and subject to the conditions set forth in this Agreement and in accordance with the DGCL, at the Effective Time, Merger Sub shall be merged with and into the Company. Following the Merger, the separate corporate existence of Merger Sub shall cease, and the Company shall continue as the surviving corporation in the Merger (the “Surviving Corporation”) and a wholly owned Subsidiary of Parent. For federal income tax purposes, it is intended that the Merger be treated as a “reorganization” pursuant to Sections 368(a)(1)(A) and 368(a)(2)(E) of the Code.

Section 2.2 **Closing.** Unless this Agreement has been terminated pursuant to, and in accordance with, Section 8.1, the closing of the Merger (the “Closing”) will take place remotely by electronic exchange of documents at 10:00 a.m., Eastern time, on the third (3rd) Business Day following the satisfaction or, to the extent permitted by applicable Law, waiver of the conditions set forth in Article VII (other than those conditions that by their terms are to be satisfied at the Closing, but subject to the satisfaction or, to the extent permitted by applicable Law, waiver of those conditions at the Closing), or at such other time, date and place as Parent and the Company may mutually agree in writing. The date on which the Closing occurs is referred to in this Agreement as the “Closing Date.”

Section 2.3 **Effective Time.** Prior to the Closing, the Company shall have delivered to Parent a duly executed certificate of merger (the “Certificate of Merger”) with respect to the Merger. Upon the terms and subject to the provisions of this Agreement, as soon as practicable on the Closing Date, Parent shall cause to be filed the Certificate of Merger with the Secretary of State of the State of Delaware (the “Delaware Secretary of State”), in accordance with the relevant provisions of the DGCL. The Merger shall become effective at such time as the Certificate of Merger is duly filed with the Delaware Secretary of State or at such other time as Parent and the Company shall mutually agree in writing and shall specify in the Certificate of Merger (the time the Merger becomes effective being the “Effective Time”).

Section 2.4 **Effects of the Merger.** The Merger shall have the effects set forth in this Agreement and in the relevant provisions of the DGCL. Without limiting the generality of the foregoing, and subject thereto, at the Effective Time, all the property, rights, privileges, immunities, powers, franchises, licenses, and authority of the Company and Merger Sub shall vest in the Surviving Corporation, and all debts, liabilities, obligations, restrictions, and duties of the Company and Merger Sub shall become the debts, liabilities, obligations, restrictions, and duties of the Surviving Corporation.

ARTICLE III EFFECT ON THE CAPITAL STOCK OF THE CONSTITUENT CORPORATIONS; EXCHANGE PROCEDURES

Section 3.1 **Conversion of Capital Stock.** At the Effective Time, by virtue of the Merger and without any action on the part of Parent, Merger Sub, the Company or the holders of any shares of capital stock of Parent, Merger Sub or the Company:

(a) Subject to Section 3.3(f), each share of Company Common Stock issued and outstanding immediately prior to the Effective Time but after giving effect to the Preferred Stock Conversion and Note Conversion (excluding any Excluded Shares or Dissenting Shares) shall thereupon be converted into and become exchangeable for solely the right to receive the number of shares of Parent Common Stock equal to the Exchange Ratio (the “Merger Consideration”). As of the Effective Time, all such shares of Company Common Stock shall no longer be outstanding and shall automatically be cancelled and shall cease to exist, and shall thereafter only represent the right to receive the Merger Consideration, any dividends or other distributions payable pursuant to Section 3.3(d) and any cash in lieu of fractional shares of Parent Common Stock payable pursuant to Section 3.3(f), in each case to be issued or paid in accordance with Section 3.3, without interest.

(b) (i) each share of Company Capital Stock (other than Company Common Stock) and (ii) each share Company Capital Stock held in the treasury of the Company or owned, directly or indirectly, by Parent, Merger Sub or any Subsidiary of the Company immediately prior to the Effective Time (collectively, “Excluded Shares”) shall automatically be cancelled and shall cease to exist, and no consideration shall be delivered in exchange therefor.

(c) Each share of common stock, par value \$0.001 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and become one validly issued, fully paid and non-assessable share of common stock, par value \$0.001 per share, of the Surviving Corporation.

(d) The Exchange Ratio shall be adjusted to reflect fully the appropriate effect of any stock split, split-up, reverse stock split (including the Parent Reverse Split (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application) to the extent such split has not been previously taken into account in calculating the Exchange Ratio), stock dividend or distribution of securities convertible into Company Capital Stock or Parent Common Stock, reorganization, recapitalization, reclassification or other like change with respect to Company Capital Stock or Parent Common Stock having a record date occurring on or after the date of this Agreement and prior to the Effective Time; provided, however, that nothing in this Section 3.1(d) shall be construed to permit the Company or Parent to take any action with respect to its securities that is prohibited by the terms of this Agreement.

(e) If any shares of Company Common Stock outstanding immediately prior to the Effective Time are unvested or are subject to a repurchase option or a risk of forfeiture under any applicable restricted stock purchase agreement or other similar agreement with the Company that does not lapse prior to the Effective Time, then the shares of Parent Common Stock issued in exchange for such shares of Company Capital Stock will to the same extent be unvested and subject to the same repurchase option or risk of forfeiture, and such shares of Parent Common Stock shall accordingly be marked with appropriate legends. The Company shall take all actions that may be necessary to ensure that, from and after the Effective Time, Parent is entitled to exercise any such repurchase option or other right set forth in any such restricted stock purchase agreement or other agreement in accordance with its terms.

(f) Prior to the Effective Time, the Company shall take all action in accordance with the Company's Organizational Documents and the DGCL necessary to convert the outstanding shares of Company Preferred Stock into the applicable number of shares of Company Common Stock in accordance with the "Conversion Price" calculated in accordance with the Company's Certificate of Incorporation such that (i) no shares of Company Preferred Stock will be issued and outstanding after giving effect to such conversion (such conversion, the "Preferred Stock Conversion"), and (ii) none of the Company, Parent or any of their respective Affiliates shall have any Liabilities in respect of such shares of Company Preferred Stock following the Preferred Stock Conversion. Prior to the Preferred Stock Conversion (and in any event no later than five (5) Business Days prior to the Closing Date), the Company shall provide Parent with true and complete drafts of all documentation pursuant to which the Company proposes to effect the Preferred Stock Conversion. The Company shall provide Parent and its counsel a reasonable opportunity to review and comment on such documentation before any such document is executed or filed with the Delaware Secretary of State, as applicable, and the Company shall give reasonable and good faith consideration to any comments made by Parent and its counsel. The Company shall provide Parent with true and complete copies of all final documentation to effect the Preferred Stock Conversion prior to the Preferred Stock Conversion.

(g) Prior to the Effective Time, the Company shall take all action in accordance with the Company Convertible Notes necessary to convert the Company Convertible Notes into the applicable number of shares of Company Common Stock in accordance with the terms of the Company Convertible Notes such that (i) no Company Convertible Notes (or any liabilities or obligations thereunder) will be outstanding after giving effect to such conversion (such conversion, the "Notes Conversion"), and (ii) none of the Company, Parent or any of their respective Affiliates shall have any liabilities or obligations in respect of such Company Convertible Notes following the Notes Conversion. Prior to the Notes Conversion (and in any event no later than ten (10) Business Days prior to the Closing Date), the Company shall provide Parent with true and complete drafts of all documentation, if any, pursuant to which the Company proposes to effect the Notes Conversion. The Company shall provide Parent and its counsel a reasonable opportunity to review and comment on such documentation before any such document is executed, and the Company shall give reasonable and good faith consideration to any comments made by Parent and its counsel. The Company shall provide Parent with true and complete copies of all final documentation, if any, to effect the Notes Conversion prior to the Notes Conversion.

Section 3.2 Treatment of Company Options and Company Warrants.

(a) At the Effective Time, each option to acquire Company Common Stock (each, a "Company Option") that is outstanding and unexercised immediately prior to the Effective Time under the Company Equity Plan or otherwise, whether or not vested, shall be converted into and become an option to purchase Parent Common Stock, and Parent shall assume each such Company Option in accordance with the terms (as in effect as of the date of the Agreement) of the Company Equity Plan and the terms of the stock option agreement by which such Company Option is evidenced. All rights with respect to Company Common Stock under Company Options assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time, each Company Option shall become an option to purchase a number of shares of Parent Common Stock determined by multiplying (i) the number of shares of Company Common Stock that were subject to such Company Option, as in effect immediately prior to the Effective Time, by (ii) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; at an exercise price per share determined by dividing (A) the per share exercise price of Company Common Stock subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; provided, however, that such conversion shall in all events occur in a manner satisfying the requirements of Sections 409A, 422 and 424 of the Code and Treasury Regulation Section 1.424-1. Except as specifically provided in this Section 3.2, following the Effective Time, each Company Option shall, if applicable, continue to be governed by the same terms and conditions as set forth in the Company Equity Plan and any agreement thereunder as were applicable immediately prior to the Effective Time; provided, however, that to the extent provided under the terms of a Company Option, such Company Option assumed by Parent in accordance with this Section 3.2(a) shall, in accordance with its terms, be subject to further adjustment as appropriate to reflect any stock split, division or subdivision of shares, stock dividend, reverse stock split, consolidation of shares, reclassification, recapitalization or other similar transaction with respect to Parent Common Stock subsequent to the Effective Time. In addition to the foregoing, Parent shall assume the Company Equity Plan, and the number and kind of shares available for issuance under the Company Equity Plan shall be converted into shares of Parent Common Stock in accordance with the adjustment provisions of the Company Equity Plan.

(b) After the Effective Time and as soon as practicable after all requisite financial statements have been filed with the SEC, Parent shall file with the SEC a registration statement on Form S-8 (or any successor form), if available for use by Parent, relating to the shares of Parent Common Stock that are either (i) issuable with respect to Company Options assumed by Parent in accordance with [Section 3.2\(a\)](#) or (ii) reserved for future grants under the Company Equity Plan.

(c) At the Effective Time, each Company Warrant that is outstanding and unexercised immediately prior to the Effective Time, if any, shall be converted into and become a warrant to purchase Parent Common Stock and Parent shall assume each such Company Warrant in accordance with its terms as adjusted by the Exchange Ratio as provided in this [Section 3.2\(c\)](#). All rights with respect to Company Capital Stock under Company Warrants assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time, each Company Warrant shall become a warrant to purchase a number of shares of Parent Common Stock, determined by multiplying (i) the number of shares of Company Common Stock that were subject to such Company Warrant, as in effect immediately prior to the Effective Time, by (ii) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; at an exercise price per share determined by dividing (A) the per share exercise price of Company Common Stock subject to such Company Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent. Except as specifically provided in this [Section 3.2](#), following the Effective Time, each Company Warrant shall, if applicable, continue to be governed by the same terms and conditions as set forth in the Company Warrant as were applicable immediately prior to the Effective Time, and such Company Warrant shall be subject to adjustment as appropriate to reflect any stock split, division, or subdivision of shares, stock dividend, reverse stock split, consolidation of shares, reclassification, recapitalization or other similar transaction with respect to Parent Common Stock subsequent to the Effective Time.

(d) Prior to the Effective Time, each of Parent and the Company shall take all action necessary (under the Company Equity Plan, Company Warrants and otherwise) to assume the Company Equity Plan by Parent and effectuate the provisions of this [Section 3.2](#). The Company shall ensure that, as of the Effective Time, no holder of a Company Option (or former holder of any such equity awards) or Company Warrant or a participant in the Company Equity Plan shall have any rights thereunder to acquire, or other rights in respect of, the capital stock of the Company, the Surviving Corporation or any of their respective Subsidiaries, or any other equity interest therein (including “phantom” stock or stock appreciation rights). As soon as practicable, following the date of this Agreement, the Company shall deliver written notice to each holder of a Company Option or Company Warrant, to the extent applicable, informing such holder of the effect of the transactions contemplated by this Agreement on the Company Options or Company Warrants, as applicable.

Section 3.3 [Exchange and Payment](#).

(a) Promptly after the Effective Time, Parent shall deposit (or cause to be deposited) with a bank, transfer agent or trust company mutually agreed to by Parent and the Company (the “[Exchange Agent](#)”), in trust for the benefit of holders of shares of Company Common Stock immediately prior to the Effective Time (other than holders to the extent they hold Excluded Shares or Dissenting Shares), book-entry shares representing the shares of Parent Common Stock issuable pursuant to [Section 3.1\(a\)](#). In addition, Parent shall make available by depositing with the Exchange Agent, as necessary from time to time after the Effective Time, any dividends or distributions payable pursuant to [Section 3.3\(d\)](#) and any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#). All shares of Parent Common Stock, dividends, distributions and cash deposited with the Exchange Agent are hereinafter referred to as the “[Exchange Fund](#).”

(b) As soon as reasonably practicable after the Effective Time, Parent shall cause the Exchange Agent to furnish to each holder of record of shares of Company Common Stock outstanding as of immediately prior to the Effective Time that were converted into the right to receive the Merger Consideration (the “[Applicable Company Shares](#)”), (i) a form of letter of transmittal in substantially the form attached as [Exhibit E](#) hereto (the “[Letter of Transmittal](#)”) and (ii) instructions for use in effecting the surrender of any certificates (each, a “[Certificate](#)”) or uncertificated shares of Company Common Stock that immediately prior to the Effective Time represented Applicable Company Shares, in exchange for (A) the Merger Consideration, (B) any dividends or other distributions payable pursuant to [Section 3.3\(d\)](#), and (C) any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#). Upon the delivery to the Exchange Agent of such Letter of Transmittal, duly completed and validly executed in accordance with the instructions thereto, together with any Certificates or other reasonable evidence of ownership of uncertificated Company Common Stock applicable to any Applicable Company Shares covered by such Letter of Transmittal, and such other documents as the Exchange Agent may reasonably require, such holder shall be entitled to receive in exchange for such Applicable Company Shares (A) that number of whole shares of Parent Common Stock to which such holder shall have become entitled pursuant to [Section 3.1\(a\)](#) (which shall be in uncertificated, book-entry form), (B) any dividends or other distributions payable pursuant to [Section 3.3\(d\)](#) and (C) any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#), and any and all Certificates so surrendered shall forthwith be cancelled. No interest will be paid or accrued on any unpaid dividends and distributions or cash in lieu of fractional shares, if any, payable to such holders of Applicable Company Shares. Until surrendered in accordance with this [Section 3.3](#), each Certificate shall be deemed after the Effective Time to represent only the right to receive the Merger Consideration payable in respect thereof, any dividends or other distributions payable pursuant to [Section 3.3\(d\)](#) and any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#).

(c) If payment of the Merger Consideration is to be made to a Person other than the Person in whose name an Applicable Company Share is registered, it shall be a condition of payment that (i) any Certificate that immediately prior to the Effective Time represented such Applicable Company Share shall be properly endorsed or shall be otherwise in proper form for transfer and (ii) such Applicable Company Share shall have been properly transferred and the Person requesting such payment shall have paid (or caused to be paid) any transfer and other Taxes required by reason of the payment of the Merger Consideration to a Person other than the holder of record of such Applicable Company Share or shall have established to the satisfaction of Parent that such Tax is not applicable.

(d) No dividends or other distributions with respect to Parent Common Stock with a record date after the Effective Time shall be paid to the holder of any Applicable Company Share with respect to the shares of Parent Common Stock that the holder thereof has the right to receive upon the surrender thereof, and no cash payment in lieu of fractional shares of Parent Common Stock shall be paid to any such holder pursuant to [Section 3.3\(f\)](#), in each case until the holder thereof shall comply with the delivery requirements set forth in this [Article III](#). Following such compliance, there shall be paid to the record holder thereof, without interest, (i) promptly after such surrender, the amount of any dividends or other distributions with a record date after the Effective Time theretofore paid with respect to such whole shares of Parent Common Stock and the amount of any cash payable in lieu of a fractional share of Parent Common Stock to which such holder is entitled pursuant to [Section 3.3\(f\)](#) and (ii) at the appropriate payment date, the amount of dividends or other distributions with a record date after the Effective Time but prior to such surrender and a payment date subsequent to such surrender payable with respect to such whole shares of Parent Common Stock.

(e) The Merger Consideration, any dividends or other distributions payable pursuant to [Section 3.3\(d\)](#) and any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#) issued and paid upon the surrender for exchange of Applicable Company Shares in accordance with the terms of this [Article III](#) shall be deemed to have been issued and paid in full satisfaction of all rights pertaining to the shares of Company Common Stock formerly represented by such Certificates or held in book-entry form. At the Effective Time, the stock transfer books of the Company shall be closed and there shall be no further registration of transfers of the shares of Company Common Stock that were outstanding immediately prior to the Effective Time. If, after the Effective Time, Certificates are presented to the Surviving Corporation or the Exchange Agent for transfer or transfer is sought for Applicable Company Shares held in book-entry form, such Certificates or book-entry shares shall be cancelled and exchanged as provided in this [Article III](#).

(f) Notwithstanding anything to the contrary contained herein, no certificates or scrip representing fractional shares of Parent Common Stock shall be issued upon the surrender for exchange of Certificates or Applicable Company Shares held in book-entry form, no dividends or other distributions with respect to the Parent Common Stock shall be payable on or with respect to any fractional share, and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a stockholder of Parent. In lieu of the issuance of any such fractional share, Parent shall pay to each former stockholder of the Company who otherwise would be entitled to receive a fractional share of Parent Common Stock an amount in cash (without interest) determined by multiplying (i) the fraction of a share of Parent Common Stock which such holder would otherwise be entitled to receive (taking into account all shares of Company Common Stock held at the Effective Time by such holder and rounded to the nearest thousandth when expressed in decimal form) pursuant to [Section 3.1\(a\)](#) by (ii) the volume weighted average price as of the close of trading of each share of Parent Common Stock traded on Nasdaq for the ten (10) consecutive trading days ending at the close of business ending on the second (2nd) trading day prior to the Closing Date.

(g) Any portion of the Exchange Fund that remains undistributed to the holders of Applicable Company Shares six (6) months after the Effective Time shall be delivered to the Surviving Corporation, upon demand, and any remaining holders of Applicable Company Shares shall thereafter look only to the Surviving Corporation, as general creditors thereof, for payment of the Merger Consideration, any unpaid dividends or other distributions payable pursuant to [Section 3.3\(d\)](#) and any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#) (subject to abandoned property, escheat or other similar laws), without interest.

(h) None of Parent, the Surviving Corporation, the Exchange Agent or any other Person shall be liable to any Person in respect of shares of Parent Common Stock, dividends or other distributions with respect thereto or cash in lieu of fractional shares of Parent Common Stock properly delivered to a Governmental Entity pursuant to any applicable abandoned property, escheat or similar Law. If any Applicable Company Shares shall not have been exchanged prior to two (2) years after the Effective Time (or immediately prior to such earlier date on which the related Merger Consideration (and all dividends or other distributions with respect to shares of Parent Common Stock and any cash in lieu of fractional shares of Parent Common Stock pursuant to this [Article III](#)) would otherwise escheat to or become the property of any Governmental Entity), any such Merger Consideration (and such dividends, distributions and cash) in respect thereof shall, to the extent permitted by applicable Law, become the property of the Surviving Corporation, free and clear of all claims or interest of any Person previously entitled thereto.

(i) The Exchange Agent shall invest any cash included in the Exchange Fund as directed by Parent on a daily basis. Any interest and other income resulting from such investments shall be paid to Parent.

(j) If any Certificate shall have been lost, stolen or destroyed, upon the making of an affidavit, in form and substance reasonably acceptable to Parent, of that fact by the Person claiming such Certificate to be lost, stolen or destroyed and, if required by Parent or the Exchange Agent, the posting by such Person of a bond in such amount as Parent or the Exchange Agent may determine is reasonably necessary as indemnity against any claim that may be made against it or the Surviving Corporation with respect to such Certificate, the Exchange Agent will deliver in exchange for such lost, stolen or destroyed Certificate the Merger Consideration payable in respect thereof, any dividends or other distributions payable pursuant to [Section 3.3\(d\)](#) and any cash in lieu of fractional shares of Parent Common Stock payable pursuant to [Section 3.3\(f\)](#).

Section 3.4 [Withholding Rights](#). Parent, Merger Sub, the Surviving Corporation, the Exchange Agent and any of their Affiliates (each, a “Payor”) shall each be entitled to deduct and withhold, or cause to be deducted and withheld, from the consideration otherwise payable to any holder of shares of Company Capital Stock, Company Options, Company Warrants or Company Convertible Notes or otherwise pursuant to this Agreement such amounts as the applicable Payor determines it is required to deduct and withhold under the Code, or any provision of state, local or foreign tax Law. To the extent that amounts are so deducted and withheld and paid over to the appropriate Governmental Entity, such amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made; *provided*, however, that, other than in respect of any withholding arising as a result of (i) the failure of the Company to deliver the certificate contemplated by Section 6.16 or (ii) the failure of any holder of shares of Company Capital Stock, Company Options, Company Warrants or Company Convertible Notes to deliver an IRS Form W-9 or Form W-8, as applicable, before making any such deduction or withholding, the applicable Payor shall use commercially reasonable efforts to provide to the Company notice of such Payor’s intention to make such deduction or withholding and such notice shall include in reasonable detail the authority, basis and method of calculation for the proposed deduction or withholding and shall be given at least a commercially reasonable period of time before such deduction or withholding is required in order for the Company to obtain reduction or relief from the applicable Governmental Entity. The Parties shall cooperate with each other to the extent reasonable to obtain a reduction of or relief from such deduction or withholding. For the avoidance of doubt, Parent may deduct or withhold in accordance with this [Section 3.4](#) by reducing the number of shares of Parent Common Stock or options to purchase shares of Parent Common Stock, as applicable, issuable to each recipient under [Section 3.1](#) or [Section 3.2](#) by the number of shares of Parent Common Stock or options to purchase Parent Common Stock, as applicable, having a fair market value on the Effective Time equal to the amount of Taxes required to be withheld with respect to the issuance of such shares or options, as applicable, to the recipient (as determined by Parent, the Surviving Corporation or the Exchange Agent). For this purpose, “fair market value” shall be determined with reference to the closing price of shares of Parent Common Stock on Nasdaq on the date immediately prior to the Closing Date.

Section 3.5 Dissenters Rights. Notwithstanding anything in this Agreement to the contrary, each share of the Company Capital Stock (other than Excluded Shares) outstanding immediately prior to the Effective Time and held by a holder who is entitled to demand and has properly demanded appraisal for such shares of the Company Capital Stock in accordance with Section 262 of the DGCL (“Dissenting Shares”), shall not be converted into or be exchangeable for the right to receive a portion of the Merger Consideration unless and until such holder fails to perfect or withdraws or otherwise loses such holder’s right to appraisal and payment under the DGCL. If, after the Effective Time, any such holder fails to perfect or withdraws or loses such holder’s right to appraisal, such Dissenting Shares shall thereupon be treated as if they had been converted as of the Effective Time into the right to receive the portion of the Merger Consideration, if any, to which such holder is entitled pursuant to Section 3.1(a), without interest. The Company shall give Parent (a) prompt written notice of any demands received by the Company for appraisal of any shares of the Company Common Stock issued and outstanding immediately prior to the Effective Time, attempted withdrawals of such demands, and any other instruments served pursuant to the DGCL and any material correspondence received by the Company relating to stockholders’ rights to appraisal with respect to the Merger and (b) the opportunity to participate in all negotiations and proceedings with respect to any exercise of such appraisal rights under the DGCL. The Company shall not, except with the prior written consent of Parent (which shall not be unreasonably withheld, conditioned or delayed), voluntarily make any payment with respect to any demands for payment of fair value for capital stock of the Company, offer to settle or settle any such demands.

Section 3.6 Further Action. If, at any time after the Effective Time, any further action is determined by the Surviving Corporation to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Corporation with full right, title and possession of and to all rights and property of the Company, then the officers and directors of the Surviving Corporation shall be fully authorized, and shall use their and its commercially reasonable efforts (in the name of the Company, in the name of Merger Sub, in the name of the Surviving Corporation and otherwise) to take such action.

ARTICLE IV REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except as set forth in the corresponding section or subsection of the disclosure letter delivered by the Company to Parent concurrently with the execution and delivery of this Agreement (the “Company Disclosure Letter”) (it being agreed that each representation and warranty in Article IV is subject to (a) any exceptions and disclosures set forth in the section or subsection of the Company Disclosure Letter corresponding to the particular section or subsection of Article IV in which such representation and warranty appears; (b) any exceptions or disclosures explicitly cross-referenced in such section or subsection of the Company Disclosure Letter by reference to another section or subsection of the Company Disclosure Letter; and (c) any exceptions or disclosures set forth in any other section or subsection of the Company Disclosure Letter to the extent it is reasonably apparent from the wording of such exception or disclosure that such exception or disclosure qualifies such representation and warranty), the Company represents and warrants to Parent as follows:

Section 4.1 Organization, Standing and Power.

(a) The Company (i) is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation, (ii) has all requisite corporate power and authority to own, lease and operate its properties and to carry on its business as now being conducted and (iii) is duly qualified or licensed to do business and is in good standing (to the extent that the concept of “good standing” is applicable in the case of any jurisdiction outside the United States) in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary, except in the case of clause (iii), where the failure to be so qualified or licensed or in good standing, individually or in the aggregate, has not had and would not reasonably be expected to have a Company Material Adverse Effect. For purposes of this Agreement, “Company Material Adverse Effect” means any event, change, circumstance, occurrence, effect or state of facts that (A) is or would reasonably be expected to be, individually or in the aggregate, materially adverse to the business, assets, liabilities, condition (financial or otherwise), or results of operations of the Company and its Subsidiaries, taken as a whole or (B) materially impairs the ability of the Company to consummate the Merger or any of the other transactions contemplated by this Agreement; provided, however, that in the case of clause (A) only, Company Material Adverse Effect shall not include any event, change, circumstance, occurrence, effect or state of facts to the extent resulting from (1) changes or conditions generally affecting the industries in which the Company and its Subsidiaries operate, or the economy or the financial, debt, banking, capital, credit or securities markets, in the United States, including effects on such industries, economy or markets resulting from any regulatory and political conditions or developments in general, (2) the outbreak or escalation of war or acts of terrorism or any natural disasters, acts of God or comparable events, (3) any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or any worsening of such epidemic, pandemic or disease outbreak or any declaration of martial law, quarantine or similar directive, policy or guidance or Law or other action by any Governmental Entity in response thereto, (4) changes in applicable Law or GAAP, or the interpretation or enforcement thereof after the date of this Agreement, (5) the public announcement of this Agreement or the pendency of this Agreement, (6) any failure, in and of itself, by the Company to meet any internal or published projections, forecasts, estimates, or predictions in respect of revenues, earnings, or other financial or operating metrics for any period (it being understood that the facts or occurrences giving rise to or contributing to such failure may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Company Material Adverse Effect, to the extent permitted by this definition and not otherwise excepted by a clause of this proviso); or (7) any specific action taken (or omitted to be taken) by the Company or any of its Subsidiaries at or with the express written direction or written consent of Parent (other than any such action or omission required by this Agreement); provided, that, with respect to clauses (1), (2), (3) and (4), the impact of such event, change, circumstance, occurrence, effect or state of facts is not disproportionately adverse to the Company and its Subsidiaries, taken as a whole, as compared to other participants in the industries in which the Company and its Subsidiaries operate.

(b) The Company has previously made available to Parent true and complete copies of the Company’s Organizational Documents and the Organizational Documents of each of its Subsidiaries, in each case as amended to the date of this Agreement, and each as so delivered is in full force and effect. The Company is not in violation of any provision of its Organizational Documents in any material respect.

Section 4.2 Capital Stock.

(a) The authorized capital stock of the Company consists of 36,000,000 shares of Company Common Stock and 28,941,797 shares of Company Preferred Stock. As of the close of business on March 29, 2023 (the “Measurement Date”), (a) (i) 4,501,652 shares of Company Common Stock and (ii) (A) 17,033,883 shares of Company Preferred Stock designated in the Company’s Certificate of Incorporation as “Series A-1 Preferred Stock” (“Series A-1 Preferred Stock”), (B) 2,916,686 shares of Company Preferred Stock designated in the Company’s Certificate of Incorporation as “Series A-2 Preferred Stock” (“Series A-2 Preferred Stock” and together with the Series A-1 Preferred Stock, the “Series A Preferred Stock”) and (C) 8,991,228 shares of Company Preferred Stock designated in the Company’s Certificate of Incorporation as “Series B Preferred Stock” (“Series B Preferred Stock”), were issued and outstanding, (b) 995,000 shares of Company Common Stock were reserved for issuance upon exercise of outstanding Company Options and (c) 440,000 shares of Company Common Stock were reserved for issuance and ungranted under the Company Equity Plan, (d) 378,982 shares of Company Common Stock were reserved for issuance upon exercise of the Company Warrants and (e) no shares of Company Common Stock were reserved for issuance upon conversion of the Company Convertible Notes. Prior to the Effective Time and after giving effect to the Preferred Stock Conversion, no shares of Company Preferred Stock will be issued or outstanding. All outstanding shares of Company Capital Stock are, and all shares of Company Common Stock reserved for issuance will be, when issued, duly authorized, validly issued, fully paid and nonassessable and not subject to any preemptive rights. All shares of Company Capital Stock, Company Options, Company Warrants and other securities of the Company have been issued and granted in material compliance with all applicable securities Laws and other applicable Laws and all requirements set forth in applicable Contracts. Other than the Company Options, the Company has not granted any equity or equity-based awards under the Company Equity Plan, including any “Stock Grants” or “Other Stock-Based Awards” (each as defined under the Company Equity Plan). Except for the Company Convertible Notes described in Section 4.2(b), neither the Company nor any of its Subsidiaries has outstanding any bonds, debentures, notes or other obligations having the right to vote (or convertible into, or exchangeable or exercisable for, securities having the right to vote) with the stockholders of the Company or such Subsidiary on any matter. Except as set forth in this Section 4.2 and except for changes since the close of business on the Measurement Date resulting from the exercise of Company Options or Company Warrants or the conversion of Company Convertible Notes, in each case described in Section 4.2(b), there are no outstanding (i) shares of capital stock or other voting securities or equity interests of the Company, (ii) securities of the Company or any of its Subsidiaries convertible into or exchangeable or exercisable for shares of Company Capital Stock or other voting securities or equity interests of the Company or any of its Subsidiaries, (iii) stock appreciation rights, “phantom” equity rights, restricted equity, performance units, interests in or rights to the ownership or earnings of the Company or any of its Subsidiaries or other equity equivalent or equity-based awards or rights, (iv) stockholder rights plan (or similar plan commonly referred to as a “poison pill”) or Contract under which the Company or any of its Subsidiaries is or may become obligated to sell or otherwise issue any shares of its capital stock or any other securities, (v) subscriptions, options, warrants, calls, commitments, Contracts or other rights to acquire from the Company or any of its Subsidiaries, or obligations of the Company or any of its Subsidiaries to issue, any shares of capital stock of the Company or any of its Subsidiaries, voting securities, equity interests or securities convertible into or exchangeable or exercisable for shares of Company Capital Stock or other voting securities or equity interests of the Company or any of its Subsidiaries or rights or interests described in the preceding clause (iv) or (vi) obligations of the Company or any of its Subsidiaries to repurchase, redeem or otherwise acquire any such securities or to issue, grant, deliver or sell, or cause to be issued, granted, delivered or sold, any such securities (other than under Company Warrants). Except for the Company Equity Plan, Company Options, and Company Warrants set forth in Section 4.2(b) of the Company Disclosure Letter, there are no stockholder agreements, voting trusts or other agreements or understandings to which the Company or any of its Subsidiaries is a party or of which the Company has Knowledge with respect to the holding, voting, registration, redemption, repurchase or disposition of, or that restricts the transfer of, any shares of Company Capital Stock or other voting securities or equity interests of the Company or any of its Subsidiaries.

(b) Section 4.2(b)(i) of the Company Disclosure Letter sets forth a true and complete list of all stockholders of the Company, as of the close of business on the Measurement Date, indicating as applicable, with respect to each such stockholder the number and class and series of shares of Company Capital Stock held by such stockholder and, with respect to the shares of Company Preferred Stock, the applicable conversion price thereon. Section 4.2(b)(ii) of the Company Disclosure Letter sets forth a true and complete list of all holders, as of the close of business on the Measurement Date, of Company Options, indicating as applicable, with respect to each such Company Option, the type of award granted (including whether it is intended to be an “incentive stock option” under Section 422 of the Code), the number of shares of Company Common Stock subject to such Company Option, the exercise or purchase price, vesting schedule, and expiration date thereof, and whether (and to what extent) the vesting of such Company Option will be accelerated by the consummation of the Merger and the other transactions contemplated by this Agreement. Section 4.2(b)(iii) of the Company Disclosure Letter sets forth a true and complete list of all holders, as of the close of business on the Measurement Date, of Company Warrants, indicating as applicable, with respect to each such Company Warrant, the number of shares of Company Common Stock subject to such Company Warrant, the exercise or purchase price, and expiration date thereof, and whether (and to what extent) any exercise or conversion of such Company Warrant will be required by the consummation of the Merger and the other transactions contemplated by this Agreement. Section 4.2(b)(iv) of the Company Disclosure Letter sets forth a true and complete list of all holders, as of the close of business on the Measurement Date, of Company Convertible Notes, indicating as applicable, with respect to each such Company Convertible Note, the number of shares of Company Common Stock subject to such Company Convertible Note, the conversion price, and expiration date thereof, and whether (and to what extent) any conversion of such Company Convertible Note will be required by the consummation of the Merger and the other transactions contemplated by this Agreement. The Company has delivered or made available to Parent a true, correct and complete copy of each Company Option, Company Warrant and Company Convertible Note. The Company has delivered or made available to Parent a true, correct and complete copy of the Company Equity Plan and the form of award agreement with respect to each Company Option. The Company does not sponsor, maintain or administer any employee or director stock option, stock purchase or equity or equity-based compensation plan or arrangement other than the Company Equity Plan. The Company is under no obligation to issue shares of Company Common Stock pursuant to any employee or director stock option, stock purchase or equity compensation plan or arrangement other than the Company Equity Plan. All grants of Company Options were validly made and properly approved by the Company Board (or a duly authorized committee or subcommittee thereof) in material compliance with all applicable Law and recorded on the Company Financial Statements in accordance with GAAP.

Section 4.3 Subsidiaries. Section 4.3 of the Company Disclosure Letter sets forth a true and complete list of each Subsidiary of the Company, including its jurisdiction of incorporation or formation. Each of the Subsidiaries of the Company (i) is an entity duly organized, validly existing and in good standing under the Laws of the jurisdiction of its organization, (ii) has all requisite corporate or similar power and authority to own, lease and operate its properties and to carry on its business as now being conducted and (iii) is duly qualified or licensed to do business and is in good standing in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary, except in the case of clause (iii), where the failure to be so qualified or licensed or in good standing, individually or in the aggregate, has not had and would not reasonably be expected to have a Company Material Adverse Effect. No shares of capital stock of the Company are owned by any Subsidiary of the Company. All outstanding shares of capital stock and equity interests or other voting securities of each Subsidiary of the Company have been duly authorized and validly issued, are fully paid, nonassessable and not subject to any preemptive rights. All outstanding shares of capital stock and equity interests or other voting securities of each such Subsidiary are owned, directly or indirectly, by the Company, free and clear of all Liens other than Permitted Liens of the Company and its Subsidiaries. Except for the capital stock of, or other equity or voting interests in, its Subsidiaries, the Company does not own, directly or indirectly, any share of capital stock, membership interest, partnership interest, joint venture interest, or other equity or voting interest in, or any interest convertible into, exercisable or exchangeable for any of the foregoing, nor is it under any current or prospective obligation to form or participate in, provide funds to, make any loan, capital contribution, guarantee, credit enhancement or other investment in, or assume any liability or obligation of, any Person. The Company does not have any outstanding equity appreciation rights, phantom equity or other equity equivalents or equity-based awards or rights that are valued in whole or in part with respect to any Subsidiary of the Company.

Section 4.4 Authority.

(a) The Company has all necessary corporate power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the Merger and the other transactions contemplated by this Agreement. The execution, delivery and performance of this Agreement by the Company and the consummation by the Company of the Merger and the other transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Company and no other corporate proceedings on the part of the Company are necessary to approve this Agreement or to consummate the Merger and the other transactions contemplated by this Agreement, subject to (i) the adoption of this Agreement by the Requisite Stockholder Vote and (ii) the approval of the Preferred Stock Conversion by the Requisite Preferred Vote, each in accordance with the Company's Organizational Documents and the DGCL (clauses (i) and (ii), the "Company Stockholder Approval"). This Agreement has been duly executed and delivered by the Company and, assuming the due authorization, execution and delivery by each of the other Parties, constitutes a valid and binding obligation of the Company, enforceable against the Company in accordance with its terms (except to the extent that enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar Laws affecting the enforcement of creditors' rights generally or by general principles of equity) (the "Enforceability Exceptions").

(b) The Company Board, at a meeting duly called and held at which all directors of the Company were present, duly and unanimously adopted resolutions: (i) approving the execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, (ii) deeming it fair to, advisable and in the best interests of the Company and its stockholders, to enter into this Agreement, (iii) directing that this Agreement be submitted to the stockholders of the Company for adoption and (iv) recommending that the stockholders of the Company vote in favor of the adoption of this Agreement and the transactions contemplated by this Agreement, including the Merger and the Preferred Stock Conversion (the "Company Board Recommendation"), which resolutions have not been subsequently rescinded, modified or withdrawn in any way.

(c) Each of the signatories to the Company Stockholder Written Consent, when delivered to Parent pursuant to Section 6.5, is an "accredited investor" for the purposes of, and within the meaning of Rule 501(a) of, Regulation D promulgated under the Securities Act.

(d) The Company Stockholder Approval obtained through the Company Stockholder Written Consent pursuant to Section 6.5 is the only vote of the holders of any class or series of the Company's shares of capital stock or other securities required in connection with the consummation of the Merger and the other transactions contemplated by this Agreement (including the Preferred Stock Conversion).

Section 4.5 No Conflict; Consents and Approvals.

(a) The, execution, delivery and performance of this Agreement by the Company does not, and the consummation of the Merger and the other transactions contemplated by this Agreement and compliance by the Company with the provisions hereof will not, conflict with, or result in any violation or breach of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of, or result in, termination, cancellation, modification or acceleration of any obligation or to the loss of a benefit under, or result in the creation of any Lien in or upon any of the properties, assets or rights of the Company or any of its Subsidiaries under, or give rise to, any increased, additional, accelerated or guaranteed rights or entitlements under, or require any consent, waiver or approval of any Person pursuant to, any provision of (i) the Company's Organizational Documents or the Organizational Documents of any Subsidiary of the Company, (ii) any Company Material Contract or (iii) subject to the governmental filings and other matters referred to in Section 4.5(b), any Law or any rule or regulation of Nasdaq applicable to the Company or any of its Subsidiaries, or by which the Company or any of its Subsidiaries, or any of their respective properties or assets, may be bound, except as, in the case of clauses (ii) and (iii), as individually or in the aggregate, would not and would not reasonably be expected to be material to the Company and its Subsidiaries, taken as a whole.

(b) No consent, approval, Order or authorization of, or registration, declaration, filing with or notice to, any Governmental Entity is required by or with respect to the Company or any of its Subsidiaries in connection with the execution, delivery and performance of this Agreement by the Company or the consummation by the Company of the Merger and the other transactions contemplated by this Agreement or compliance with the provisions hereof, except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware as required by the DGCL and (ii) such other consents, approvals, Orders, authorizations, registrations, declarations, filings or notices the failure of which to be obtained or made, individually or in the aggregate, would not and would not reasonably be expected to be material to the Company and its Subsidiaries, taken as a whole.

Section 4.6 Financial Statements.

(a) Section 4.6 of the Company Disclosure Letter includes true and complete copies of the following financial statements (such financial statements, the “Company Financial Statements”): (i) the audited consolidated balance sheets of the Company and its Subsidiaries as of December 31, 2020 and December 31, 2021 and the related audited consolidated statements of operation, comprehensive loss, members’ equity and cash flows for the fiscal year or relevant period ended December 31, 2020 and December 31, 2021, respectively, together with all of the related notes and schedules thereto, accompanied by the reports thereon of the Company’s independent auditors, and (ii) the unaudited consolidated balance sheets of the Company and its subsidiaries as of December 31, 2022 and the related unaudited consolidated statements of operation, comprehensive loss, members’ equity and cash flows for the fiscal year or relevant period ended December 31, 2022, together with all of the related notes and schedules thereto, if any.

(b) The Company and each of its Subsidiaries maintains a system of internal control over financial reporting designed to provide reasonable assurance that (i) transactions are executed with management’s authorization, (ii) transactions are recorded as necessary to permit preparation of the consolidated financial statements in conformity with GAAP and to maintain accountability for the Company’s consolidated assets, (iii) access to assets of the Company and its Subsidiaries is permitted only in accordance with management’s authorization, and (iv) the reporting of assets of the Company and its Subsidiaries is compared with existing assets at regular intervals. The books and records of the Company and its Subsidiaries have been, and are being, maintained in all material respects in accordance with GAAP (to the extent applicable) and any other applicable legal and accounting requirements and reflect only actual transactions.

(c) Neither the Company nor any of its Subsidiaries has extended or maintained credit, arranged for the extension of credit, modified or renewed an extension of credit, in the form of a personal loan or otherwise, to or for any manager or executive officer (or equivalent) of the Company.

(d) The Company Financial Statements (i) have been prepared in a manner consistent with the books and records of the Company and its Subsidiaries, (ii) have been prepared in accordance with GAAP applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto), and (iii) present fairly, in all material respects, the consolidated financial position of the Company and its Subsidiaries as of the dates thereof and their respective consolidated results of operations and cash flows for the periods then ended, in accordance with GAAP, except as disclosed therein.

(e) Since January 1, 2020, neither the Company nor any of its Subsidiaries nor, to the Knowledge of the Company, any director, officer, or auditor, of the Company or any of its Subsidiaries has received or otherwise had or obtained Knowledge of any material complaint, allegation, assertion or claim, whether written or oral, regarding the accounting or auditing practices, procedures, methodologies or methods of the Company or any of its Subsidiaries or their respective internal accounting controls, including any material complaint, allegation, assertion or claim that the Company or any of its Subsidiaries has engaged in questionable accounting or auditing practices.

(f) Neither the Company nor any of its Subsidiaries is a party to, or has any commitment to become a party to, any joint venture, off balance sheet partnership or any similar Contract (including any Contract or arrangement relating to any transaction or relationship between or among the Company and any of its Subsidiaries, on the one hand, and any unconsolidated Affiliate, including any structured finance, special purpose or limited purpose entity or Person, on the other hand, or any “off balance sheet arrangements” (as defined in Item 303(a) of Regulation S-K under the Exchange Act)), where the result, purpose or intended effect of such Contract is to avoid disclosure of any material transaction involving, or material liabilities of, the Company or any of its Subsidiaries in the Company’s or such Subsidiary’s financial statements.

(g) As of the date of this Agreement, the consolidated Indebtedness for borrowed money of the Company and its Subsidiaries is \$11,459,735.

Section 4.7 No Undisclosed Liabilities. Neither the Company nor any of its Subsidiaries has any liabilities or obligations of any nature, whether accrued, absolute, contingent or otherwise, known or unknown, whether due or to become due of a nature that would be required to be recorded or reflected on a balance sheet under GAAP, except (a) to the extent specifically disclosed, reflected, accrued or reserved against in the unaudited consolidated balance sheet of the Company and its Subsidiaries as of December 31, 2022 included in the Company Disclosure Letter, or (b) (i) incurred in the ordinary course of business consistent with past practice since December 31, 2022 that are not material to the Company and its Subsidiaries, taken as a whole, (ii) resulting from performance by the Company or its Subsidiaries required under a Contract made available to Parent prior to the date of this Agreement or entered into after the date of this Agreement in compliance with covenants set forth in Section 6.1(a) (other than as a result of a breach or violation by the Company or its Subsidiaries), or (iii) incurred in connection with the transactions contemplated by this Agreement.

Section 4.8 Certain Information. None of the information supplied or to be supplied by or on behalf of the Company specifically for inclusion or incorporation by reference in (i) the Registration Statement will, at the time the Registration Statement is filed with the SEC, at the time of any amendment or supplement thereto and at the time the Registration Statement (or any post-effective amendment or supplement) becomes effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they are made, not misleading or (ii) the Proxy Statement will, at the date it is first mailed to the Parent stockholders or at the time of the Parent Stockholders’ Meeting, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading. Notwithstanding the foregoing, the Company makes no representation or warranty with respect to statements included or incorporated by reference in the Registration Statement or Proxy Statement based on information supplied in writing by or on behalf of Parent or Merger Sub specifically for inclusion or incorporation by reference therein.

Section 4.9 Absence of Certain Changes or Events. Since December 31, 2022 through the date of this Agreement: (a) except in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, the Company and its Subsidiaries have conducted their businesses only in the ordinary course consistent with past practice, (b) there has not been any Company Material Adverse Effect and (c) none of the Company or any of its Subsidiaries has taken any action, that if taken after the date of this Agreement, would constitute a breach of any covenants set forth in Sections 6.1(a).

Section 4.10 Litigation. There is no legal, administrative, arbitral, or other proceeding, suit, action, investigation, arbitration, written claim, audit, hearing, written charge, complaint, indictment, litigation, or examination (each, an “Action”) pending or threatened in writing against or affecting the Company or any of its Subsidiaries, or any of their respective properties or assets, that (a) if adversely determined, individually or in the aggregate, would reasonably be likely to result in material liability to the Company and its Subsidiaries, taken as a whole, or (b) seeks material injunctive or other material non-monetary relief. None of the Company, any of its Subsidiaries, or any of their respective properties or assets, is subject to any material outstanding Order. As of the date of this Agreement, there is no Action pending or threatened in writing seeking to prevent, hinder, modify, delay or challenge the Merger or any of the other transactions contemplated by this Agreement. There are no internal investigations or internal inquiries that, since January 1, 2020, have been conducted or are being conducted by or at the direction of the Company Board (or any committee thereof) regarding any material accounting practices of the Company or any of its Subsidiaries. For the avoidance of doubt, this Section 4.10 shall not apply to Taxes or the Company Plans.

Section 4.11 Compliance with Laws. The Company and each of its Subsidiaries are, and since January 1, 2020 have been, in compliance in all material respects with all Laws applicable to their businesses, operations, properties or assets. None of the Company or any of its Subsidiaries has received, since January 1, 2020, a written notice or other written communication alleging or relating to a potential material violation of any Law applicable to their businesses, operations, properties or assets. The Company and each of its Subsidiaries have in effect all material permits, licenses, variances, exemptions, applications, approvals, authorizations, registrations, formulary listings, consents, operating certificates, franchises, Orders and approvals granted by any Governmental Entities (collectively, “Permits”) necessary for them to own, lease or operate their properties and assets and to carry on their businesses and operations as now conducted, including, as applicable, all Permits for the development, clinical testing, manufacturing, marketing, distribution and importation or exportation, as currently conducted, of any of its Products or Product candidates. There has occurred no material violation of, default (with or without notice or lapse of time or both) under or event giving to others any right of revocation, non-renewal, adverse modification or cancellation of, with or without notice or lapse of time or both, any such Permit, nor would any such revocation, non-renewal, adverse modification or cancellation result from the consummation of the transactions contemplated by this Agreement. No Action is pending or, to the Knowledge of the Company, threatened, which seeks to revoke, limit, suspend, or materially modify any Company Permit.

Section 4.12 Regulatory Matters.

(a) The Company's and its Subsidiaries' Product candidates are being and have been developed, tested, manufactured, packaged, labeled, stored, imported, and exported in compliance in all material respects with all applicable Laws, including, but not limited to (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and its implementing regulations, such as regulations relating to good laboratory practice, good clinical practice, and good manufacturing practice, (ii) applicable sections of the Public Health Service Act (42 U.S.C. § 201 et seq.) and its implementing regulations; the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. § 17921 et seq.), (iii) any other applicable Laws governing research, development, investigational use, record keeping, reporting, testing, specification development, manufacturing, processing, packaging, labeling, storage, importation, transportation, handling, or export of investigational drug products (collectively, "Regulatory Laws"), as well as (iv) any applicable Permits of the Company or any of its Subsidiaries, including but not limited to investigational new drug applications or their national or foreign equivalents. All such Company Permits are in full force and effect, and to the Knowledge of the Company, no Governmental Entity has threatened to limit, suspend or revoke any Company Permit.

(b) Neither the Company nor any of its Subsidiaries has (i) received or been subject to any action, notice, citation, suspension, revocation, warning, administrative proceeding or investigation by a Governmental Entity or other Person that alleges or asserts that the Company or any of its Subsidiaries has violated any applicable Regulatory Laws or which requires or seeks any adjustment, modification or alteration in the Company's or any of its Subsidiaries' Product candidates or in the Company's or any of its Subsidiaries' operations, activities, or services that has not been resolved, including any notice of inspectional observations, FDA warning letter or untitled letter or any similar notices or (ii) been subject to a corporate integrity agreement, deferred prosecution agreement, consent decree, settlement agreement or other similar agreements or Orders mandating or prohibiting future or past activities. Neither the Company nor any of its Subsidiaries has settled, or agreed to settle, any actions brought by any Governmental Entity or any other Person for a violation of any applicable Regulatory Laws, nor is any such action pending resolution. As of the date hereof, (i) there are no restrictions imposed by any Governmental Entity upon the business, activities or services of the Company or any of its Subsidiaries that restrict the Company's or any of its Subsidiaries' business operations, (ii) the Company or any of its Subsidiaries and their respective Product candidates are not, and have not been, otherwise subject to any other enforcement actions taken by the FDA or any other Governmental Entity, and (iii) to the Knowledge of the Company, there are no facts that would reasonably be expected to give rise to such an event as described in the immediately preceding clause (i) or (ii).

(c) The Company and its Subsidiaries have timely filed all material reports, statements, documents, registrations, filings, amendments, supplements and submissions required to be filed by them under applicable Regulatory Laws or the terms of any Company Permits. Each such filing complied in all material respects with applicable Regulatory Laws as of the date of submission and was true, complete and correct as of the date of submission, and no deficiencies have been asserted in writing by any applicable Governmental Entity with respect to any such filings, submissions, reports or related information. Any material and legally necessary or required updates, changes, corrections, amendments, supplements or modifications to such filings required to be submitted by the Company or any of its Subsidiaries have been submitted thereby to the applicable Governmental Entity or appropriate third party.

(d) All nonclinical studies and clinical trials conducted or sponsored by or on behalf of the Company or any of its Subsidiaries have been, and if still pending are being, conducted in material compliance with applicable research protocols and all applicable Regulatory Laws and Company Permits, including standards for conducting non-clinical laboratory studies, standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials (including for the protection of the rights and welfare of human subjects), and all applicable Laws restricting the use and disclosure of health information. No nonclinical study or clinical trial conducted or sponsored by or on behalf of the Company or its Subsidiaries with respect to any of the Company's Product candidates has been terminated or suspended prior to completion due to safety or other non-business reasons, and, to the Knowledge of the Company, there are no facts that could give rise to such a determination. No Governmental Entity, institutional review board, ethics committee, independent monitoring committee, or institutional animal care and use committee has provided notice that it has initiated or, to the Knowledge of the Company, is threatening to initiate any action to place a hold order on, or otherwise terminate, delay, suspend or modify any such ongoing nonclinical or clinical testing, and, to the Knowledge of the Company, there are no facts that would reasonably be expected to give rise to such action.

(e) Neither the Company nor any of its Subsidiaries, nor, to the Knowledge of the Company, any officer, employee, or agent of the Company or any of its Subsidiaries (including Persons engaged by the Company for contract research, contract manufacturing, consulting, or other collaboration services), has made an untrue statement of a material fact or a fraudulent statement to the FDA or any other Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or such other Governmental Entity, or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy.

(f) Neither the Company nor its Subsidiaries, nor, to the Knowledge of the Company, any officer, employee, clinical investigator, or agent of the Company or its Subsidiaries has been debarred under 21 U.S.C. § 335a or any similar applicable Law or convicted of any crime or engaged in any conduct for which debarment is mandated or authorized by 21 U.S.C. § 335a or any similar applicable Law. Neither the Company nor any of its Subsidiaries, nor, to the Knowledge of the Company, any officer, employee, clinical investigator, or agent of the Company or any of its Subsidiaries, has been excluded from participation in any federal health care program, or any similar foreign program, or has been convicted of any crime or engaged in any conduct for which such Person would reasonably be expected to be excluded from participating in any federal health care program under Section 1128 of the Social Security Act of 1935, as amended, or any similar applicable Law or program. Neither the Company nor any of its Subsidiaries is, and, to the Knowledge of the Company, no officer, employee, clinical investigator, or agent of the Company or any of its Subsidiaries is subject to an investigation or proceeding by any Governmental Entity that would reasonably be expected to result in any such suspension, exclusion, or debarment, as applicable, and there are no facts, to the Knowledge of the Company, that would reasonably be expected to give rise to such suspension, exclusion, or debarment.

Section 4.13 Benefit Plans.

(a) Section 4.13(a) of the Company Disclosure Letter contains a true and complete list of each material Company Plan. For purposes of this Agreement, “Company Plan” means each “employee benefit plan” (within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”), whether or not subject to ERISA), “multiemployer plans” (within the meaning of ERISA Section 3(37)), and all pension, retirement, stock purchase, stock option, phantom stock or other equity or equity-based plan, severance, employment, consulting, collective bargaining, change-in-control, retiree medical, retiree dental, retiree vision, retiree life insurance, retention, fringe benefit, bonus, incentive, nonqualified deferred compensation, supplemental retirement, health, life, or disability insurance, dependent care, welfare and all other employee benefit and compensation plans, agreements, programs, policies or other arrangements, whether or not subject to ERISA, whether formal or informal, written or oral, legally binding or not, under which any Relevant Service Provider (or any of their dependents) has any present or future right to compensation or benefits, in any case, that the Company, any of its Subsidiaries or any of their respective ERISA Affiliates sponsors or maintains, or is required to sponsor or maintain, is making contributions to or is required to make contributions to, or with respect to which the Company or any of its Subsidiaries has any present or future liability or obligation (contingent or otherwise). The Company has provided or made available to Parent a current, accurate and complete copy of each material Company Plan (including, without limitation, the Company Equity Plan and the forms of all award agreements evidencing outstanding Company Options), or if such Company Plan is not in written form, a written summary of all of the material terms of such Company Plan. With respect to each Company Plan, the Company has furnished or made available to Parent a current, accurate and complete copy of, to the extent applicable: (i) any related trust agreement or other funding instrument, (ii) the most recent determination, opinion or advisory letter of the Internal Revenue Service (the “IRS”), (iii) the current summary plan description and summary of material modifications thereto, and (iv) for the three most recent years (A) the Form 5500 and attached schedules, (B) audited financial statements, (C) actuarial valuation reports, (D) nondiscrimination testing reports and (iv) all correspondences and filings concerning IRS or Department of Labor or other Governmental Entity audits or investigations.

(b) Neither the Company, its Subsidiaries or any of their respective ERISA Affiliates sponsors, maintains, contributes to or is required to sponsor, maintain or contribute to, or has in the past six (6) years sponsored, maintained, contributed to or been required to sponsor, maintain or contribute to, or has any liability (contingent or otherwise) with respect to: (i) a “multiemployer plan” (within the meaning of ERISA Section 3(37)), (ii) an “employee pension benefit plan,” within the meaning of Section 3(2) of ERISA (“Pension Plan”) that is subject to Title IV of ERISA or Section 412 of the Code, (iii) a Pension Plan which is a “multiple employer plan” as defined in Section 413 of the Code, (iv) a “funded welfare plan” (within the meaning of Section 419 of the Code) or (v) a “multiple employer welfare arrangement” (within the meaning of Section 3(40) of ERISA).

(c) With respect to the Company Plans:

(i) each Company Plan complies in all material respects with its terms and complies in all material respects in form and in operation with the applicable provisions of ERISA and the Code and all other applicable legal requirements;

(ii) each Company Plan intended to be qualified under Section 401(a) of the Code has received a favorable determination, advisory and/or opinion letter, as applicable, from the IRS that it is so qualified and nothing has occurred since the date of such letter that would reasonably be expected to result in the loss of the qualified status of such Company Plan;

(iii) there is no Action (including any investigation, audit or other administrative proceeding) by the Department of Labor, the Pension Benefit Guaranty Corporation (the “PBGC”), the IRS or any other Governmental Entity or by any plan participant or beneficiary pending, or to the Knowledge of the Company, threatened, relating to the Company Plans, any fiduciaries thereof with respect to their duties to the Company Plans or the assets of any of the trusts under any of the Company Plans (other than non-material routine claims for benefits) and to the Knowledge of the Company there have been no non-exempt prohibited transactions under Section 406 of ERISA or Section 4975 of the Code that could result in a material Tax or penalty;

(iv) none of the Company Plans currently provides, or has any liability to provide, post-termination or retiree medical, dental, vision, prescription drug, life insurance or other welfare benefits to any individual for any reason, except as may be required by Section 601, *et seq.* of ERISA and Section 4980B(b) of the Code or other applicable similar law regarding health care coverage continuation (collectively “COBRA”), and none of the Company, its Subsidiaries or any of their respective ERISA Affiliates has any liability to provide post-termination or retiree medical, dental, vision, prescription drug, life insurance or other welfare benefits to any individual, except to the extent required by COBRA;

(v) each Company Plan that is a group health plan under Section 733(a)(1) of ERISA and Section 5000(b)(1) of the Code complies with the Patient Protection and Affordable Care Act (“ACA”), COBRA, and the Health Insurance Portability and Accountability Act of 1996. The Company has not incurred (whether or not assessed) or is not reasonably expected to incur or be subject to any Tax, penalty or other liability that may be imposed under the ACA or Sections 4980B, 4980D, 4980H, 6721 or 6722 of the Code or with respect to a requirement to timely file ACA information returns with the IRS or provide statements to participants under Section 6056 or 6055 of the Code or state law requirements as applicable, or pursuant to Sections 4976 through 4980 of the Code or Title I of ERISA with respect to any Company Plans; and

(vi) each Company Plan is subject exclusively to United States Law.

(d) Neither the execution and delivery of this agreement nor the consummation of the merger will, either alone or in combination with any other event, (A) entitle any Relevant Service Provider to any compensation, payment or benefit, (B) accelerate the time of payment or vesting, or increase the amount of or otherwise enhance any compensation or benefit due any such Relevant Service Provider, (C) increase any amount of compensation or benefits otherwise payable under any company plan or otherwise or (D) require any contribution or payment to fund any obligation under any company plan or otherwise.

(e) Neither the Company nor any Subsidiary is a party to any Contract, arrangement or plan (including any Company Plan) that may reasonably be expected to result, separately or in the aggregate, in connection with the transactions contemplated by this Agreement (either alone or in combination with any other events), in the payment of any “parachute payments” within the meaning of Section 280G of the Code. There is no Contract, plan or other arrangement to which any of the Company or any Subsidiary is a party or by which any of them is otherwise bound (including under any Company Plan) to compensate any person in respect of Taxes or other liabilities incurred with respect to Section 409A or 4999 of the Code.

(f) Each Company Plan that is a nonqualified deferred compensation plan under Section 409A of the Code has been administered and operated in all material respects in documentary and operational compliance with the provisions of Section 409A of the Code and the regulations thereunder. No Tax penalties or additional Taxes have been imposed or would be reasonably expected to be imposed on any Relevant Service Provider, and no acceleration of Taxes has occurred or would be reasonably expected to occur with respect to any Relevant Service Provider, in each case as a result of a failure to comply with Section 409A of the Code with respect to any Company Plan that is a “nonqualified deferred compensation plan” within the meaning of Section 409A of the Code.

Section 4.14 Labor Matters.

(a) The Company and its Subsidiaries are and at all times since January 1, 2020 have been in compliance in all material respects with all applicable Laws relating to labor and employment, including those relating to wages, hours, collective bargaining, unemployment compensation, workers compensation, equal employment opportunity, age and disability discrimination, work authorization and immigration, employee classification, employee privacy, occupational safety and health, payment and withholding of Taxes and COBRA.

(b) Neither the Company nor any of its Subsidiaries is a party to, or otherwise bound by, an effective or pending collective bargaining agreement or similar agreement with a union or labor organization or other person purporting to act as exclusive bargaining representative of any Company employees, and no employee of the Company or any of its Subsidiaries is covered by any such agreement. To the Knowledge of the Company, there has not been any activity on behalf of any labor union, labor organization or similar employee group to organize any employees of the Company or any of its Subsidiaries. There are, and during the past three (3) years have been, no (i) unfair labor practice charges or complaints against the Company or any of its Subsidiaries pending before the National Labor Relations Board or any other labor relations tribunal or authority, (ii) representation claims or petitions or demands for recognition pending before the National Labor Relations Board or any other labor relations tribunal or authority, or (iii) material grievances or pending arbitration proceedings against the Company or any of its Subsidiaries that arose out of or under any collective bargaining agreement and to the Knowledge of the Company, no such charges, complaints, claims, petitions, demands, arbitrations or grievances have been threatened. During the preceding three (3) years, there has not been, and as of the date of this Agreement there is not pending or, to the Knowledge of the Company, threatened, any labor dispute, work stoppage, labor strike or lockout against the Company or any of its Subsidiaries by employees.

(c) To the Knowledge of the Company, no current employee or officer of the Company or any of its Subsidiaries has notified the Company or any of its Subsidiaries of or expressed any plans to, or is expected to, terminate his or her employment relationship with such entity following the consummation of the transactions contemplated by this Agreement.

(d) Since January 1, 2020, (i) neither the Company nor any Subsidiary has effectuated a “plant closing” (as defined in the Worker Adjustment Retraining and Notification Act of 1988, as amended (the “WARN Act”)) or any similar state or local Law, affecting any site of employment or one or more facilities or operating units within any site of employment or facility, (ii) there has not occurred a “mass layoff” (as defined in the WARN Act) in connection with the Company or any Subsidiary affecting any site of employment or one or more facilities or operating units within any site of employment or facility and (iii) neither the Company nor any Subsidiary has engaged in layoffs or employment terminations sufficient in number to trigger application of any similar state, local or foreign Law. Each Person employed by the Company or any Subsidiary is properly classified as exempt or non-exempt in accordance with applicable overtime Laws, and no Person treated as an independent contractor or consultant by the Company or any Subsidiary should have been properly classified as an employee under applicable law.

(e) There are no Actions against the Company or any of its Subsidiaries pending, or to the Knowledge of the Company, threatened to be brought or filed, in connection with the employment or engagement of any current or former employee, officer, consultant or other service provider of the Company, including, without limitation, any claim relating to employment discrimination, harassment, retaliation, workers’ compensation, occupational safety and health, equal pay, employment classification or any other employment related matter arising under applicable Laws, except where such Action would not, individually or in the aggregate, result in the Company incurring a material liability.

(f) Except as set forth in Section 4.14(f) of the Company Disclosure Letter or with respect to any Company Plan (which subject is addressed in Section 4.13 above), the execution of this Agreement and the consummation of the transactions set forth in or contemplated by this Agreement will not result in any breach or violation of, or cause any payment to be made under, any applicable Laws respecting labor and employment or any collective bargaining agreement to which the Company or any of its Subsidiaries is a party.

(g) Except as set forth in Section 4.14(g) of the Company Disclosure Letter, since January 1, 2020, (i) no written allegations or, to the Knowledge of the Company, verbal allegations of workplace sexual harassment, sexual misconduct, discrimination or retaliation have been made, initiated, filed or, to the Knowledge of the Company, threatened against the Company, any of its Subsidiaries or any of their respective current or former directors, officers or senior level management employees, (ii) to the Knowledge of the Company, no incidents of any workplace sexual harassment, sexual misconduct, discrimination or retaliation have occurred, and (iii) neither the Company nor any of its Subsidiaries have entered into any settlement agreement related to allegations of workplace sexual harassment, sexual misconduct, discrimination or retaliation by any of their directors, officers or employees described in clause (i) hereof or any independent contractor.

Section 4.15 Environmental Matters.

(a) Except as, individually or in the aggregate, is not and would not reasonably be expected to be material to the Company and its Subsidiaries, taken as a whole (i) the Company and each of its Subsidiaries are, and since January 1, 2020 have conducted their respective businesses, in compliance with all, and have not violated any, applicable Environmental Laws; except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to result in a Company Material Adverse Effect; (ii) the Company and its Subsidiaries have obtained all Permits of all Governmental Entities and any other Person that are required under any Environmental Law ("Environmental Permits"), except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to result in a Company Material Adverse Effect, and there has occurred no violation of or default under any such Environmental Permit giving to others any right of revocation, non-renewal, adverse modification or cancellation of any such Environmental Permit, nor, to the Knowledge of the Company, would any such revocation, non-renewal, adverse modification or cancellation result from the consummation of the Merger or any other transactions contemplated by this Agreement; (iii) to the Knowledge of the Company, there has been no Release of, or exposure of any Person to, any Hazardous Substance by the Company or any of its Subsidiaries or, to the Knowledge of the Company, any other Person in any manner that has given or would reasonably be expected to give rise to any remedial or investigative obligation, corrective action requirement or liability of the Company or any of its Subsidiaries under applicable Environmental Laws; (iv) neither the Company nor any of its Subsidiaries has received any written claims, notices, demand letters or requests for information (except for such claims, notices, demand letters or requests for information the subject matter of which has been resolved prior to the date of this Agreement) from any Governmental Entity or any other Person asserting that the Company or any of its Subsidiaries is in violation of, or has known, alleged or potential liability under, any Environmental Law; or (v) to the Knowledge of the Company, no Hazardous Substance has been disposed of, arranged to be disposed of, Released or transported by or on behalf of the Company or any of its Subsidiaries in violation of any applicable Environmental Law, or in a manner that has given rise to, or that would reasonably be expected to give rise to, any liability under any Environmental Law, in each case, on, at, under or from any current properties or facilities owned, leased or operated by the Company or any of its Subsidiaries or, to the Knowledge of the Company, as a result of any operations or activities of the Company or any of its Subsidiaries at any other location.. To the extent applicable, the Company has made available to Parent copies of all material environmental documents (including reports of assessments, audits, investigations or sampling, notices of violation, and Environmental Permits) in the Company's possession or control with respect to actual or potential liability pursuant to applicable Environmental Law.

(b) As used in this Agreement, "Environmental Law" means any Law relating to (i) the protection, preservation or restoration of the environment (including air, surface water, groundwater, drinking water supply, surface and subsurface soils and strata, wetlands, plant and animal life or any other natural resource) or (ii) the exposure to, or the use, storage, recycling, treatment, generation, transportation, processing, handling, labeling, production, manufacture, sale, distribution, Release or disposal of Hazardous Substances or products containing Hazardous Substances.

(c) As used in this Agreement, “Hazardous Substance” means any hazardous or toxic substance, material or waste, pollutant or contaminant, including, petroleum, petroleum constituents and products, per- and polyfluoroalkyl substances (PFAS), medical, biomedical, biohazardous, carcinogenic, radiological or radioactive materials, substances or wastes, asbestos or asbestos-containing materials or products, polychlorinated biphenyls, and lead or lead-based paints or materials, any of the foregoing to the extent regulated by applicable Environmental Law.

(d) As used in this Agreement, “Release” means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, depositing, disposing, dispersing, or migrating into or through the environment or within any building, structure, facility or fixture.

Section 4.16 Taxes.

(a) The Company and each of its Subsidiaries have timely (i) filed all material Tax Returns required to be filed by any of them and all material Tax Returns filed by, or on behalf of, the Company and its Subsidiaries are true, accurate and complete in all material respects; and (ii) paid in full (or caused to be timely paid in full) all material Taxes that are required to be paid by or with respect to them, whether or not such Taxes were shown as due on such Tax Returns.

(b) All material Taxes not yet due and payable by the Company and its Subsidiaries as of December 31, 2022 have been, in all respects, properly accrued in accordance with GAAP on Company Financial Statements. Since December 31, 2022, the Company and each of its Subsidiaries have not incurred, individually or in the aggregate, any liability for material Taxes outside the ordinary course of business consistent with past practice.

(c) Neither the Company nor any of its Subsidiaries has executed any waiver of any statute of limitations on, or extended the period for the assessment or collection of, any amount of Tax, in each case that has not since expired.

(d) No audits or other investigations, proceedings, claims, assessments or examinations by any Governmental Entity (each, a “Tax Action”) with respect to material Taxes or any material Tax Return of the Company or any of its Subsidiaries are presently in progress or have been asserted, threatened or proposed in writing. No deficiencies or claims for material Taxes have been claimed, proposed, assessed or asserted in writing against the Company or any of its Subsidiaries by a Governmental Entity, other than any such claim, proposal, assessment or assertion that has been satisfied by payment in full, settled or withdrawn.

(e) The Company and each of its Subsidiaries have timely withheld all material Taxes required to have been withheld from payments made (or deemed made) to its employees, independent contractors, creditors, equityholders and other third parties and, to the extent required, such Taxes have been timely paid to the relevant Governmental Entity.

(f) Neither the Company nor any of its Subsidiaries has engaged in a “listed transaction” as set forth in Treasury Regulation § 1.6011-4(b)(2).

(g) Neither the Company nor any of its Subsidiaries (i) is a party to or bound by, or currently has any liability pursuant to, any Tax sharing, allocation or indemnification agreement or obligation, other than any such agreement or obligation entered into in the ordinary course of business the primary purpose of which is unrelated to Taxes; (ii) is, or has been, a member of a group (other than a group the common parent of which is the Company or one of the Company’s Subsidiaries) filing a consolidated, combined, affiliated, unitary or similar income Tax Return; (iii) has any liability for the Taxes of any Person (other than the Company and its Subsidiaries) pursuant to Treasury Regulation § 1.1502-6 (or any similar provision of state, local or non-United States Law) as a transferee or successor, or otherwise by operation of Law; or (iv) is, or has been, treated as a resident for any income Tax purpose, or as subject to Tax by virtue of having a permanent establishment, an office or fixed place of business, in any country other than the country in which it was or is organized.

(h) No private letter rulings, technical advice memoranda, or similar agreements or rulings have been requested, entered into or issued by any taxing authority with respect to the Company or any of its Subsidiaries which rulings remain in effect.

(i) Neither the Company nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of (i) a change in, or use of improper, method of accounting requested or initiated on or prior to the Closing Date, (ii) a “closing agreement” as described in Section 7121 of the Code (or any similar provision of Law) executed on or prior to the Closing Date, (iii) an installment sale or open transaction disposition made on or prior to the Closing Date, (iv) any prepaid amount received or deferred revenue accrued on or prior to the Closing Date, (v) any income earned as a result of transactions or events occurring in a taxable period (or portion thereof) ending on or prior to the Closing Date that would result in an inclusion under Section 951(a) or Section 951A of the Code; or (vi) an election under Section 965 of the Code.

(j) There are no Liens for Taxes upon any of the assets of the Company or any of its Subsidiaries other than Permitted Liens.

(k) None of the Company or any of its Subsidiaries has distributed stock of another Person or has had its stock distributed by another Person in the three (3) year period ending prior to the Closing, in a transaction that was purported or intended to be governed in whole or in part by Sections 355 or 361 of the Code.

(l) The Company and each of its Subsidiaries have conducted all intercompany transactions, and maintained all related documentation, in compliance with Section 482 of the Code (or any similar provision of applicable Law).

(m) Neither the Company nor any of its Subsidiaries knows of any fact, agreement, plan or other circumstance that could reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(n) No claim has been made in writing by any Governmental Entity in a jurisdiction where neither the Company nor any of its Subsidiaries currently files, or has filed, a Tax Return, that the Company or any of its Subsidiaries is, or may be, subject to taxation by such jurisdiction.

(o) No Subsidiary of the Company is a “passive foreign investment company” within the meaning of Section 1297 of the Code.

(p) Neither the Company nor any of its Subsidiaries has engaged in a trade or business, had a permanent establishment (within the meaning of an applicable Tax treaty or convention), or otherwise been subject to taxation in any country other than the country of its formation.

(q) Neither the Company nor any of its Subsidiaries is a party to any joint venture, partnership, or other arrangement that is treated as a partnership for federal or foreign income Tax purposes.

(r) The Company is and has been since its formation properly treated as a “C corporation” for U.S. federal and applicable state tax purposes. The U.S. federal income tax classification of each Subsidiary of the Company is set forth on [Schedule 4.16\(r\)](#).

For purposes of this [Section 4.16](#), where the context permits, each reference to the Company and its Subsidiaries shall include a reference to any Person for whose Taxes the Company or its Subsidiaries are liable under applicable Law.

Section 4.17 [Contracts](#).

(a) [Section 4.17\(a\)](#) of the Company Disclosure Letter identifies each Contract to which the Company or any of its Subsidiaries is a party, or by which the Company or any of its Subsidiaries is bound, that constitutes a Company Material Contract as of the date of this Agreement. For purposes of this Agreement, each of the following to which the Company or any its Subsidiaries is a party or by which it is bound as of the date of this Agreement constitutes a “[Company Material Contract](#)”:

(i) any Contract that is a settlement, conciliation or similar agreement with or approved by any Governmental Entity and pursuant to which (A) the Company or any of its Subsidiaries will be required after the date of this Agreement to pay any monetary obligations or (B) that contains material obligations or limitations on the conduct of the Company or its Subsidiaries;

(ii) any Contract (A) by its terms limiting the freedom or right of the Company or any of its Subsidiaries or Affiliates to engage in any line of business or to compete with any other Person in any location or line of business, (B) containing any “most favored nations” terms and conditions (including with respect to pricing) granted by the Company or any of its Subsidiaries, or (C) containing exclusivity obligations or otherwise limiting the freedom or right of the Company or any of its Subsidiaries or Affiliates to sell, distribute or manufacture any products or services for any other Person;

(iii) any Contract that requires by its terms or is reasonably expected to require the payment or delivery of cash or other consideration to the Company or any of its Subsidiaries in an amount having an expected value in excess of \$100,000 in the fiscal year ending December 31, 2023 or by the Company or any of its Subsidiaries in an amount having an expected value in excess of \$100,000 in the fiscal year ending December 31, 2023 and in each case which cannot be cancelled by the Company or its Subsidiaries without penalty or further payment without more than ninety (90) days' notice;

(iv) any Contract relating to Indebtedness for borrowed money in excess of \$100,000 (whether incurred, assumed, guaranteed or secured by any asset) of the Company or any of its Subsidiaries or creating any material Liens with respect to any assets of the Company or any of its Subsidiaries;

(v) any Contract with any Person constituting a joint venture, collaboration, partnership or similar profit sharing arrangement or requiring any Person to develop or commercialize any product, technology or service;

(vi) any Contract (excluding any Company Plan) that by its express terms requires the Company or any of its Subsidiaries, or any successor to, or acquirer of, the Company or any of its Subsidiaries, to make any payment to another Person as a result of a change of control of the Company or any of its Subsidiaries, as applicable (a "Company Change of Control Payment") or gives another Person a right to receive or elect to receive a Company Change of Control Payment;

(vii) any Contract that prohibits the declaration or payment of dividends or distributions in respect of the limited liability company interests, capital stock or other equity interests of the Company or its Subsidiaries, the pledging of the limited liability company interests, capital stock or other equity interests of the Company or its Subsidiaries or the issuance of any guaranty by the Company or any of its Subsidiaries;

(viii) any material (A) in-bound license (other than Commercially Available Software) and (B) out-bound license of Intellectual Property Rights (other than non-exclusive licenses granted by the Company or any of its Subsidiaries in the ordinary course of business);

(ix) any Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$100,000 pursuant to its express terms;

(x) any Contract relating to the disposition or acquisition of assets or rights (including equity interests) except for sales of inventory in the ordinary course of business;

(xi) any Contract pursuant to which the Company or any of its Subsidiaries leases or subleases any material real property;

(xii) any Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to the Company in connection with this Agreement and the transactions contemplated hereby;

(xiii) any Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of the Company or any of its Subsidiaries; or

(xiv) any Contract requiring payment by or to the Company or any of its Subsidiaries after the date of this Agreement in excess of \$100,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Company or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, collaboration, development or other agreement currently in force under which the Company or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which the Company or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Company or any of its Subsidiaries; or (D) license granted to any third party to manufacture or produce any product, service or technology of the Company or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of the Company or any of its Subsidiaries, in each case, except for Contracts entered into in the ordinary course of business consistent with past practice;

(xv) any Contract granting a right of first refusal, right of first offer, or similar right with respect to any assets of a Person or that contains any provision requiring the purchase of all or a material portion of requirements for a given product or service from another Person; or

(xvi) any other Contract that is currently in effect and would be required to be filed by the Company as an exhibit pursuant to Item 601(b)(10) of Regulation S-K under the Securities Act or that would be required to be disclosed under Item 404 of Regulation S-K under the Securities Act (assuming in each case such requirements were applicable to the Company).

(b) (i) Each Company Material Contract is valid and binding on the Company and any of its Subsidiaries to the extent such Subsidiary is a party thereto, as applicable, and to the Knowledge of the Company, each other party thereto, and is in full force and effect and enforceable in accordance with its terms, subject to the Enforceability Exceptions; (ii) the Company and each of its Subsidiaries, and, to the Knowledge of the Company, each other party thereto, has performed all material obligations required to be performed by it under each Company Material Contract; and (iii) there is no material default under any Company Material Contract by the Company or any of its Subsidiaries or, to the Knowledge of the Company, any other party thereto, and to the Company's Knowledge, no event or condition has occurred that constitutes, or, after notice or lapse of time or both, would constitute, a material default on the part of the Company or any of its Subsidiaries or, to the Knowledge of the Company, any other party thereto under any such Company Material Contract, nor has the Company or any of its Subsidiaries received any written notice of any such material default, event or condition. The Company has furnished or made available to Parent true and complete copies of all Company Material Contracts, including all amendments thereto.

Section 4.18 Insurance. The Company and each of its Subsidiaries is covered by valid and currently effective insurance policies issued in favor of the Company or one or more of its Subsidiaries that are customary and adequate for companies of similar size in the industries and locations in which the Company operates. Section 4.18 of the Company Disclosure Letter sets forth, as of the date hereof, a true and complete list of all material insurance policies issued in favor of the Company or any of its Subsidiaries, or pursuant to which the Company or any of its Subsidiaries is a named insured or otherwise a beneficiary, as well as any historic occurrence-based policies still in force. With respect to each such insurance policy, (a) such policy is in full force and effect and all premiums due thereon have been paid, and (b) neither the Company nor any of its Subsidiaries is in breach or default, and has not taken any action or failed to take any action which (with or without notice or lapse of time, or both) would constitute such a breach or default, or would permit termination or modification of, any such policy. Other than customary end of policy notifications from insurance carriers, since January 1, 2020, no notice of cancellation or termination have been received with respect to any such policy. This Section 4.18 shall not apply to insurance relative to any Company Plan.

Section 4.19 Properties.

(a) The Company or one of its Subsidiaries has good and valid title to, or in the case of leased property and leased tangible assets and properties, a valid leasehold interest in, all of its real properties and tangible assets and properties that are necessary for the Company and its Subsidiaries to conduct their respective businesses as currently conducted, free and clear of all Liens other than Permitted Liens of the Company and its Subsidiaries, and the material tangible personal property currently used in the operation of the business of the Company and its Subsidiaries is in good working order (reasonable wear and tear excepted).

(b) Each of the Company and its Subsidiaries has complied with the terms of all real property leases to which it is a party (the “Company Real Property Leases”), and all such leases are in full force and effect, except for any such noncompliance or failure to be in full force and effect that, individually or in the aggregate, has not had and would not reasonably be expected to have a Company Material Adverse Effect. Each of the Company and its Subsidiaries enjoys peaceful and undisturbed possession under all such leases, except for any such failure to do so that, individually or in the aggregate, has not had and would not reasonably be expected to have a Company Material Adverse Effect.

(c) The Company does not own any real property. Section 4.19(c) of the Company Disclosure Letter sets forth a true and complete list of all Company Real Property Leases.

This Section 4.19 does not relate to Intellectual Property matters, which matters are the subject of Section 4.20.

Section 4.20 Intellectual Property; Data Privacy.

(a) Section 4.20(a) of the Company Disclosure Letter sets forth a true and complete list of all (i) patents and patent applications; (ii) trademark registrations and applications; (iii) copyright registrations and applications; (iv) domain names, in each case, owned or purported to be owned by the Company or any of its Subsidiaries ((i)-(iv) collectively, “Company Registered IP”), indicating for each, (a) the name (or names for co-applicants/registrants/owners) of applicant/registrant and current owner, (b) the applicable jurisdiction, registration number (or application number), (c) the date issued (and date filed) and (d) the status (including the next action or payment and date due); and (v) a true and complete list of all unregistered Trademarks owned or purported to be owned by the Company or any of its Subsidiaries that is material to the business. (A) All of the Company Registered IP is subsisting and, to the Knowledge of the Company, valid and enforceable, in the case of any Company Registered IP that is registered or issued, (B) no Company Registered IP is involved in any interference, reissue, derivation, reexamination, opposition, cancellation or similar Action and, to the Knowledge of the Company, no such Action is threatened with respect to any of the Company Registered IP and (C) except as set forth on Section 4.20(a), the Company or its Subsidiaries own exclusively, free and clear of any and all Liens (other than Permitted Liens of the Company and its Subsidiaries), all Company Owned IP. All Company Registered IP is in compliance in all material respects with all legal requirements (including the timely filing of responses, statements or affidavits of use and incontestability and renewal applications and required fees with respect to Trademarks and the payment of filing, examination, maintenance and other fees and the filing of responses, declarations and affidavits and compliance with any duty of disclosure with respect to Patents), have not been adjudged to be invalid or unenforceable in whole or in part, and are not subject to any fees, responses or actions falling due within ninety (90) days after the Closing Date.

(b) The Company and its Subsidiaries have taken commercially reasonable measures to maintain the confidentiality of all information that constitutes or constituted a material Trade Secret of the Company or its Subsidiaries, including requiring all Persons having access thereto to execute written non-disclosure agreements or other binding obligations to maintain confidentiality of such information. There has been no unauthorized disclosure to any third party of any material confidential information or Trade Secrets owned by the Company or its Subsidiaries, except where such disclosure was permitted by Law. All of the material Company Owned IP has been created by employees of the Company or its Subsidiaries within the scope of their employment or by independent contractors of the Company or its Subsidiaries or other Persons providing services to the Company or its Subsidiaries who have executed contracts that expressly and irrevocably assign, using present tense assignment language, all right, title, and interest in such Company Owned IP on a worldwide, royalty-free basis. To the Knowledge of the Company, no current or former employee, consultant, contractor, or potential partner or investor of the Company or its Subsidiaries is in unauthorized possession of any of the material confidential information, Trade Secrets or software included in the Company Owned IP. To the Knowledge of the Company, no current or former independent contractor engaged by the Company or its Subsidiaries or other Person that has provided services to the Company or its Subsidiaries (x) created any Company Owned IP using the equipment, supplies, facilities, confidential information or Intellectual Property of, or in the course of work for, any other employer of or Person engaging the services of such independent contractor or such other Person that has provided services to the Company or its Subsidiaries where such use would affect the Company's or its Subsidiaries' rights in such Company Owned IP or (y) in providing such services, violated any agreement between such independent contractor or such other Person and any other employer of or Person engaging the services of such independent contractor or such other Person.

(c) (i) All material Company Owned IP is free and clear of any covenants not to sue, encumbrances, joint ownership obligations or duties, or Action (other than (A) those occurring in the ordinary course of seeking and maintaining patents and other registrations of Intellectual Property, (B) Permitted Liens and (C) out-bound license of Intellectual Property Rights listed in Section 4.17(a)(viii)(B)), (ii) to the Knowledge of the Company, the conduct of the businesses of the Company and its Subsidiaries, including the manufacture of the Company Manufactured Products, has not in the past six (6) years infringed, misappropriated or diluted, and does not infringe, misappropriate or dilute, any Intellectual Property of any Person, (iii) in the prior six (6) years, neither the Company nor any of its Subsidiaries has received any written notice or claim asserting or suggesting that any such infringement, misappropriation, or dilution is, or may be, occurring or has, or may have, occurred, (iv) to the Knowledge of the Company, no Person is infringing, misappropriating, or diluting in any material respect any Company Owned IP, and (v) in the past six (6) years, neither the Company nor its Subsidiaries has threatened to bring, and neither the Company nor its Subsidiaries has brought, any Action regarding the ownership, use, validity or enforceability of any Company Owned IP. Except as set forth on Section 4.20(c) of the Company Disclosure Letter, to the Knowledge of the Company, no Abbreviated New Drug Application referencing any Product of Company or any of its Subsidiaries has been submitted to the FDA.

(d) All software included in Company Owned IP that is material to the business of the Company and its Subsidiaries (“Company Software”) and, to the Knowledge of the Company, all software licensed from third parties that is material to the business of the Company and its Subsidiaries, is free from any significant defect or significant programming or documentation error, operates and runs in a reasonable and efficient business manner, conforms in all material respects to the specifications thereof, if applicable, and, with respect to the Company Software, the Company or its Subsidiaries possess or have rights to use, as applicable, the source code, system documentation, statements of principles of operation and schematics, as well as any pertinent commentary, explanation, program (including compilers), workbenches, tools and higher level (or “proprietary”) language used for the development, maintenance, and implementation thereof, so that a trained computer programmer could reasonably be expected to maintain, support, compile and deploy the same, except in each case where such defect or error, or failure to operate or run, failure to conform, or failure to possess or have such rights would not have a Company Material Adverse Effect. No ownership rights in the Company Software have been transferred to any third party. The Company or its Subsidiaries is the sole and exclusive owner of the entire and unencumbered right, title, and interest in the Company Software created by the Company or its Subsidiaries. The Company or its Subsidiaries has the right to use all software development tools, library functions, compilers, and other third party software that are currently used in the operation and/or modification of the Company Software. The Company and its Subsidiaries have used commercially reasonable efforts to prevent the introduction into the Company Software and software licensed from third parties, and such Company Software does not contain, any unauthorized “back door,” “drop dead device,” “time bomb,” “Trojan horse,” “virus” or “worm” (as such terms are commonly understood in the software industry) or any other unauthorized code designed or intended to have any of the following functions: disrupting or disabling the operation of, or providing unauthorized access to, a computer system or network or other device on which such code is stored or installed.

(e) (i) The Company and its Subsidiaries have taken commercially reasonable steps to protect the confidentiality and security of the computer and information technology systems used by the Company and its Subsidiaries (the “Company IT Systems”) and the information and transactions stored or contained therein or transmitted thereby, (ii) to the Knowledge of the Company, since January 1, 2020, there has been no unauthorized, unlawful, accidental or improper use, loss, destruction, disclosure, access, transmittal, modification, acquisition, unavailability, compromise or corruption of any information or data (including, without limitation, Personal Information and confidential information) stored, maintained or otherwise Processed (a “Security Incident”) by the Company and its Subsidiaries and (iii) since January 1, 2020, there have been no material failures, crashes, viruses, or actual or reasonably suspected Security Incidents affecting the Company IT Systems. The Company IT Systems function in accordance with their specifications without material defects or errors when used in accordance with such specifications and related documentation. The Company and its Subsidiaries have taken reasonable precautions to protect the confidentiality, integrity and security of the Company IT Systems and all data and information stored or contained therein or transmitted thereby, including exercising reasonable care and due diligence in selecting third party service providers to host, maintain and protect Company IT Systems and to provide commercially reasonable business continuity and disaster recovery services. Since January 1, 2020, there has been no continued substandard performance of any Company IT Systems which has caused the substantial disruption or interruption in or to the use of the Company IT Systems or the operation of the business of the Company and its Subsidiaries. The Company IT Systems are in good working condition and are sufficient for the operation of the business of the Company and its Subsidiaries as currently conducted.

(f) Since January 1, 2020, the Company and its Subsidiaries have at all times complied in all material respects with all applicable Privacy Commitments. Neither this Agreement nor the consummation of the transactions contemplated by this Agreement will materially breach any Privacy Laws.

(g) The Company and its Subsidiaries have established and maintain, and/or have exercised reasonable care and due diligence in selecting third party service providers to establish and maintain, commercially reasonable technical, physical and organizational measures designed to protect Company Data collected, used or held for use by the Company or its Subsidiaries, or to which the Company or its Subsidiaries have access or otherwise Process, against loss and unauthorized access, use, modification, disclosure, Processing or other misuse.

(h) Since January 1, 2020, neither the Company nor any of its Subsidiaries have experienced any material Data Security Breach.

(i) Neither the Company nor any of its Subsidiaries has received any written Order, request, warning, reprimand, inquiry, notification, allegation, or claim alleging that it is in violation of or has not complied, in any material respect, with any Privacy Commitment. Neither the Company nor any of its Subsidiaries has receive been notified that it is currently and neither the Company nor any of its Subsidiaries have previously been notified that they are under investigation, or subject to any complaint, audit, proceeding, investigation, enforcement action, inquiry or claim, initiated by any (a) Governmental Entity, (b) state, federal or foreign self-regulating body, or (c) any Person, regarding or alleging that the Processing of Personal Information by the Company or any of its Subsidiaries is in violation of any Privacy Commitment. No Person has claimed or, to the Knowledge of the Company or any of its Subsidiaries, threatened to claim, any material amount of compensation (or an offer for compensation) from the Company or any of its Subsidiaries under or in connection with any actual or alleged violation of any Privacy Commitment.

(j) To the Knowledge of the Company, no government funding, facilities or resources of a university, college, other educational institution or research center or funding from third parties was used in the development of the Company Owned IP, or to the Knowledge of the Company, exclusively licensed to the Company, and no Governmental Entity, university, college, other educational institution or research center has, to the Knowledge of the Company, any claim or right in or to such Intellectual Property.

(k) Except as set forth on Section 4.20(k) of the Company Disclosure Letter, the execution, delivery and performance by the Company of this Agreement, and the consummation of the transactions contemplated by this Agreement, will not result in the loss of, or give rise to, any right of any Third Person to terminate or modify any of the Company's or any Subsidiaries' rights or obligations under any agreement under which the Company or any of its Subsidiaries grants to any Person, or any Person grants to the Company or any of its Subsidiaries, a license or right under or with respect to any Intellectual Property that is material to any of the businesses of the Company or any of its Subsidiaries.

Section 4.21 State Takeover Statutes.

(a) None of the Company nor any of the Company’s “Affiliates” or “Associates” directly or indirectly “owns,” beneficially or otherwise (in each case, as those terms are defined in Section 203 of the DGCL), and at all times during the three (3)-year period prior to the date of this Agreement, none of the Company’s “Affiliates” or “Associates” directly or indirectly has “owned,” beneficially or otherwise, any Parent Common Stock.

(b) The Company Board has taken and will take all actions so that the restrictions applicable to business combinations contained in Section 203 of the DGCL with respect to the Company are, and will be, inapplicable to the execution, delivery and performance of this Agreement and the timely consummation of the Merger and the other transactions contemplated by this Agreement. No other “moratorium,” “fair price,” “business combination,” “control share acquisition” or similar provision of any state anti-takeover Law (collectively, “Takeover Laws”) or any similar anti-takeover provision in the Company’s Organizational Documents is, or at the Effective Time will be, applicable to this Agreement, the Merger or any of the other transactions contemplated by this Agreement.

Section 4.22 Related Party Transactions.

(a) Section 4.22(a) of the Company Disclosure Letter describes any material transactions or relationships, since January 1, 2020, between, on one hand, the Company or any of its Subsidiaries and, on the other hand, any (i) executive officer or director of the Company or any of its Subsidiaries or any of such executive officer’s or director’s immediate family members, (ii) owner of more than five percent (5%) of the voting power of the outstanding shares of Company Capital Stock or (iii) to the Knowledge of the Company, any “related person” (within the meaning of Item 404 of Regulation S-K under the Securities Act) of any such officer, director or owner (other than the Company or its Subsidiaries) in the case of each of (i), (ii) or (iii) that is of the type that would be required to be disclosed under Item 404 of Regulation S-K under the Securities Act.

(b) Section 4.22(b) of the Company Disclosure Letter lists each stockholders’ agreement, voting agreement, registration rights agreement, co-sale agreement or other similar Contract between the Company and any holders of shares of Company Capital Stock, including any such Contract granting any Person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights (collectively, the “Investor Agreements”).

Section 4.23 Certain Payments. Neither the Company nor any of its Subsidiaries (nor, to the Knowledge of the Company, any of their respective directors, executives, representatives, agents or employees) (a) has used or is using any corporate funds for any illegal contributions, gifts, entertainment or other unlawful expenses relating to political activity, (b) has used or is using any corporate funds for any direct or indirect unlawful payments to any foreign or domestic governmental officials or employees, (c) has violated, or is violating, any provision of the Foreign Corrupt Practices Act of 1977, (d) has established or maintained, or is maintaining, any unlawful fund of corporate monies or other properties or (e) has made any bribe, unlawful rebate, payoff, influence payment, kickback or other unlawful payment of any nature.

Section 4.24 Brokers. No broker, investment banker, financial advisor or other Person is entitled to any broker's, finder's, financial advisor's, opinion, success, transaction or other similar fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of the Company or any of its Affiliates.

Section 4.25 Opinion of Financial Advisor. No broker, investment banker, financial advisor or other Person has issued an opinion to the Company with respect to the fairness of the Exchange Ratio to the holders of Company Capital Stock.

Section 4.26 No Other Representations or Warranties. Except for the representations and warranties set forth in Article V (as qualified by the Parent Disclosure Letter) and any certificate delivered by Parent pursuant to Section 7.3(c), the Company acknowledges and agrees that none of Parent, its Subsidiaries or any other Person on behalf of the Parent or any of its Subsidiaries makes any other express or implied representation or warranty, express or implied, at law or in equity, with respect to any of it or any of its assets, liabilities or operations, and any such other representations or warranties are expressly disclaimed, and the Company has not relied on any such information or any representation or warranty not set forth in Article V (as qualified by the Parent Disclosure Letter) or in any certificate delivered by Parent pursuant to Section 7.3(c).

ARTICLE V REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Except (a) as disclosed in the Parent SEC Documents filed or furnished to the SEC and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system at least three (3) Business Days prior to the date of this Agreement and that is reasonably apparent on the face of such disclosure to be applicable to the representation and warranty set forth herein (other than any disclosures contained or referenced therein under the captions "Risk Factors," "Forward-Looking Statements," "Quantitative and Qualitative Disclosures About Market Risk," and any other disclosures contained or referenced therein of information, factors, or risks that are predictive, cautionary, or forward-looking in nature); or (b) as set forth in the corresponding section or subsection of the disclosure letter delivered by Parent to the Company concurrently with the execution and delivery of this Agreement (the "Parent Disclosure Letter") (it being agreed that each representation and warranty in Article V is subject to (a) any exceptions and disclosures set forth in the section or subsection of the Parent Disclosure Letter corresponding to the particular section or subsection of Article V in which such representation and warranty appears; (b) any exceptions or disclosures explicitly cross-referenced in such section or subsection of the Parent Disclosure Letter by reference to another section or subsection of the Parent Disclosure Letter; and (c) any exceptions or disclosures set forth in any other section or subsection of the Parent Disclosure Letter to the extent it is reasonably apparent from the wording of such exception or disclosure that such exception or disclosure qualifies such representation and warranty), Parent and Merger Sub represent and warrant to the Company as follows:

Section 5.1 Organization, Standing and Power.

(a) Each of Parent and Merger Sub (i) is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation, (ii) has all requisite corporate power and authority to own, lease and operate its properties and to carry on its business as now being conducted and (iii) is duly qualified or licensed to do business and is in good standing (to the extent that the concept of “good standing” is applicable in the case of any jurisdiction outside the United States) in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary, except in the case of clause (iii), where the failure to be so qualified or licensed or in good standing, individually or in the aggregate, has not had and would not reasonably be expected to have a Parent Material Adverse Effect. For purposes of this Agreement, “Parent Material Adverse Effect” means any event, change, circumstance, occurrence, effect or state of facts that (A) is or would reasonably be expected to be, individually or in the aggregate, materially adverse to the business, assets, liabilities, condition (financial or otherwise), or results of operations of Parent and its Subsidiaries, taken as a whole or (B) materially impairs the ability of Parent to consummate the Merger or any of the other transactions contemplated by this Agreement; provided, however, that in the case of clause (A) only, Parent Material Adverse Effect shall not include any event, change, circumstance, occurrence, effect or state of facts to the extent resulting from (1) changes or conditions generally affecting the industries in which Parent and its Subsidiaries operate, or the economy or the financial, debt, banking, capital, credit or securities markets, in the United States, including effects on such industries, economy or markets resulting from any regulatory and political conditions or developments in general, (2) the outbreak or escalation of war or acts of terrorism or any natural disasters, acts of God or comparable events, (3) any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or any worsening of such epidemic, pandemic or disease outbreak, or any declaration of martial law, quarantine or similar directive, policy or guidance or Law or other action by any Governmental Entity in response thereto, (4) changes in applicable Law or GAAP, or the interpretation or enforcement thereof after the date of this Agreement, (5) the public announcement of this Agreement or the pendency of this Agreement, (6) any failure, in and of itself, by Parent to meet any internal or published projections, forecasts, estimates, or predictions in respect of revenues, earnings, or other financial or operating metrics for any period (it being understood that the facts or occurrences giving rise to or contributing to such failure may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Parent Material Adverse Effect, to the extent permitted by this definition and not otherwise excepted by a clause of this proviso); (7) any change, in and of itself, in the market price or trading volume of Parent’s securities or in its credit ratings (it being understood that the facts or occurrences giving rise to or contributing to such change may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Parent Material Adverse Effect, to the extent permitted by this definition and not otherwise excepted by a clause of this proviso); or (8) any specific action taken (or omitted to be taken) by Parent or any of its Subsidiaries at or with the express written direction or written consent of the Company (other than any such action or omission required by this Agreement); provided, that, with respect to clauses (1), (2), (3) and (4), the impact of such event, change, circumstance, occurrence, effect or state of facts is not disproportionately adverse to Parent and its Subsidiaries, taken as a whole, as compared to other participants in the industries in which Parent and its Subsidiaries operate.

(b) Parent has previously made available to the Company true and complete copies of the Organizational Documents of Parent, and the Organizational Documents of each Subsidiary of Parent, including Merger Sub, in each case as amended to the date of this Agreement, and each as so delivered is in full force and effect. Neither Parent nor Merger Sub is in violation of any provision of its Organizational Documents in any material respect.

Section 5.2 Capital Stock.

(a) The authorized capital stock of Parent consists of 1,000,000,000 shares of Parent Common Stock and 30,000,000 shares of preferred stock, par value \$0.001 per share (the "Parent Preferred Stock"). As of the close of business on the Measurement Date, (a) 2,039,878 shares of Parent Common Stock (excluding treasury shares) were issued and outstanding, (b) no shares of Parent Common Stock were held by Parent in its treasury, (c) no shares of Parent Preferred Stock were issued and outstanding and no shares of Parent Preferred Stock were held by Parent in its treasury, (d) 246,575 shares of Parent Common Stock were reserved for issuance pursuant to the Parent Equity Plan (of which 109,824 shares were subject to outstanding unexercised Parent Options and 1,754 shares were subject to outstanding unsettled restricted stock units denominated in Parent Common Stock (each, a "Parent RSU")), and (e) 88,253 shares of Parent Common Stock were reserved for issuance upon exercise of warrants to acquire shares of Parent Common Stock (the "Parent Warrants"). All outstanding shares of capital stock of Parent are, and all shares of Parent Common Stock reserved for issuance will be, when issued, duly authorized, validly issued, fully paid and nonassessable and not subject to any preemptive rights. All shares of Parent Common Stock, Parent Options, Parent RSUs, Parent Warrants and other securities of Parent have been issued and granted in material compliance with all applicable securities Laws and other applicable Laws and all requirements set forth in applicable Contracts. Other than the Parent Options and the Parent RSUs, Parent has not granted any equity or equity-based awards under the Parent Equity Plan, including any "Stock Grants" or "Other Stock-Based Awards" (each as defined under the Parent Equity Plan). All shares of Parent Common Stock to be issued in connection with the Parent Stock Issuance, when so issued in accordance with the terms of this Agreement, will be duly authorized, validly issued, fully paid and nonassessable and not subject to any preemptive rights. Except as set forth above in this Section 5.2, neither Parent nor any of its Subsidiaries has outstanding any bonds, debentures, notes or other obligations having the right to vote (or convertible into, or exchangeable or exercisable for, securities having the right to vote) with the stockholders of Parent or such Subsidiary on any matter. Except as set forth above in this Section 5.2(a) and except for changes since the close of business on the Measurement Date resulting from the exercise of any Parent Options or Parent Warrants or settlement of Parent RSUs, in each case described in this Section 5.2(a), there are no outstanding (i) shares of capital stock or other voting securities or equity interests of Parent, (ii) securities of Parent or any of its Subsidiaries convertible into or exchangeable or exercisable for shares of capital stock of Parent or other voting securities or equity interests of Parent or any of its Subsidiaries, (iii) stock appreciation rights, "phantom" equity rights, restricted equity, performance units, interests in or rights to the ownership or earnings of Parent or any of its Subsidiaries or other equity equivalent or equity-based awards or rights, (iv) stockholder rights plan (or similar plan commonly referred to as a "poison pill") or Contract under which Parent or any of its Subsidiaries is or may become obligated to sell or otherwise issue any shares of its capital stock or any other securities, (v) subscriptions, options, warrants, calls, commitments, Contracts or other rights to acquire from Parent or any of its Subsidiaries, or obligations of Parent or any of its Subsidiaries to issue, any shares of capital stock of Parent or any of its Subsidiaries, voting securities, equity interests or securities convertible into or exchangeable or exercisable for shares of capital stock or other voting securities or equity interests of Parent or any of its Subsidiaries or rights or interests described in the preceding clause (iii) or (vi) obligations of Parent or any of its Subsidiaries to repurchase, redeem or otherwise acquire any such securities or to issue, grant, deliver or sell, or cause to be issued, granted, delivered or sold, any such securities (other than under the Parent Equity Plan and any award agreements issued thereunder). Except for the Parent Equity Plan, Parent Options, Parent RSUs, Parent Warrants and other agreements set forth in Section 5.2(b) of the Parent Disclosure Letter, there are no stockholder agreements, voting trusts or other agreements or understandings to which Parent or any of its Subsidiaries is a party or of which Parent has Knowledge with respect to the holding, voting, registration, redemption, repurchase or disposition of, or that restricts the transfer of, any shares of capital stock or other voting securities or equity interests of Parent or any of its Subsidiaries.

(b) Section 5.2(b)(i) of the Parent Disclosure Letter sets forth a true and complete list of all holders, as of the close of business on the Measurement Date, of Parent Options, indicating as applicable, with respect to each such Parent Option, the type of award granted (including whether it is intended to be an “incentive stock option” under Section 422 of the Code), the number of shares of Parent Common Stock subject to such Parent Option, the exercise or purchase price, vesting schedule, and expiration date thereof, and whether (and to what extent) the vesting of such Parent Option will be accelerated by the consummation of the Merger and the other transactions contemplated by this Agreement. Section 5.2(b)(ii) of the Parent Disclosure Letter sets forth a true and complete list of all holders, as of the close of business on the Measurement Date, of Parent Warrants, indicating as applicable, with respect to each such Company Warrant, the number of shares of Parent Common Stock subject to such Parent Warrant, the exercise or purchase price, and expiration date thereof, and whether (and to what extent) any exercise or conversion of such Parent Warrant will be required by the consummation of the Merger and the other transactions contemplated by this Agreement. Section 5.2(b)(iii) of the Parent Disclosure Letter sets forth a true and complete list of all holders, as of the close of business on the Measurement Date, of Parent RSUs, indicating with respect to each such Parent RSU, the number of shares of Parent Common Stock subject to such Parent RSU, the date of grant or issuance and the vesting schedule and expiration date applicable to such Parent RSU.

(c) The Parent has delivered or made available to Company a true, correct and complete copy of each Parent Option, Parent Warrant and Parent RSU. The Parent has delivered or made available to Company a true, correct and complete copy of the Parent Equity Plan and the form of award agreement with respect to each Parent Option. The Parent does not sponsor, maintain or administer any employee or director stock option, stock purchase or equity or equity-based compensation plan or arrangement other than the Parent Equity Plan. The Parent is under no obligation to issue shares of Parent Common Stock pursuant to any employee or director stock option, stock purchase or equity compensation plan or arrangement other than the Parent Equity Plan. All grants of Parent Options were validly made and properly approved by the Parent Board (or a duly authorized committee or subcommittee thereof) in material compliance with all applicable Law and recorded on the Parent Financial Statements in accordance with GAAP.

Section 5.3 Subsidiaries. Section 5.3 of the Parent Disclosure Letter sets forth a true and complete list of each Subsidiary of Parent, including its jurisdiction of incorporation or formation. Each of the Subsidiaries of Parent (i) is an entity duly organized, validly existing and in good standing under the Laws of the jurisdiction of its organization, (ii) has all requisite corporate or similar power and authority to own, lease and operate its properties and to carry on its business as now being conducted and (iii) is duly qualified or licensed to do business and is in good standing in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary, except in the case of clause (iii), where the failure to be so qualified or licensed or in good standing, individually or in the aggregate, has not had and would not reasonably be expected to have a Parent Material Adverse Effect. No shares of capital stock of Parent are owned by any Subsidiary of Parent. All outstanding shares of capital stock and other voting securities or equity interests of each Subsidiary of Parent have been duly authorized and validly issued, are fully paid, nonassessable and not subject to any preemptive rights. All outstanding shares of capital stock and other voting securities or equity interests of each such Subsidiary are owned, directly or indirectly, by Parent, free and clear of all Liens other than Permitted Liens of Parent and its Subsidiaries. Except for the capital stock of, or other equity or voting interests in, its Subsidiaries, Parent does not own, directly or indirectly, any share of capital stock, membership interest, partnership interest, joint venture interest, or other equity or voting interest in, or any interest convertible into, exercisable or exchangeable for any of the foregoing, nor is it under any current or prospective obligation to form or participate in, provide funds to, make any loan, capital contribution, guarantee, credit enhancement or other investment in, or assume any liability or obligation of, any Person. Except as set forth in Section 5.3 of the Parent Disclosure Letter, Parent does not have any outstanding equity appreciation rights, phantom equity or other equity equivalents or equity-based awards or rights that are valued in whole or in part with respect to any Subsidiary of Parent.

Section 5.4 Authority.

(a) Each of Parent and Merger Sub has all necessary corporate power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the Merger and the other transactions contemplated by this Agreement, including the Parent Stock Issuance. The execution, delivery and performance of this Agreement by Parent and Merger Sub and the consummation by Parent and Merger Sub of the Merger and the other transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of Parent and Merger Sub and no other corporate proceedings on the part of Parent or Merger Sub are necessary to approve this Agreement or to consummate the Merger and the other transactions contemplated by this Agreement, subject, in the case of the consummation of the Merger, to (i) (x) the approval of the Parent Stock Issuance and, if necessary, a “change of control” for purposes of Nasdaq Rule 5635(b) by the affirmative vote of the majority of the total votes cast by the holders of Parent Common Stock and (y) the approval of the Parent Reverse Split by a majority of the outstanding shares of Parent Common Stock (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application) (collectively, the “Parent Stockholder Approval”) and (ii) the approval of this Agreement by Parent as the sole stockholder of Merger Sub. This Agreement has been duly executed and delivered by Parent and, assuming the due authorization, execution and delivery by the other Parties, constitutes a valid and binding obligation of Parent, enforceable against Parent in accordance with its terms (except to the extent that enforceability may be limited by the Enforceability Exceptions).

(b) The Parent Board, at a meeting duly called and held at which all directors of Parent were present, duly and unanimously adopted resolutions (i) approving the execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger and (ii) recommending that the stockholders of Parent vote in favor of the Parent Stockholder Matters, which resolutions have as of the date hereof not been subsequently rescinded, modified or withdrawn in any way, except as may be expressly permitted by [Section 6.3](#) (the recommendation in this clause (ii), the “[Parent Board Recommendation](#)”).

(c) The Merger Sub Board, acting by written consent, duly and unanimously adopted resolutions (i) approving the execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, (ii) deeming it fair to, advisable and in the best interests of Parent, in its capacity as the sole stockholder of Merger Sub, to enter into this Agreement, and (iii) recommending that Parent, in its capacity as the sole stockholder of Merger Sub, vote in favor of the adoption of this Agreement and the transactions contemplated by this Agreement, including the Merger, which resolutions have as of the date hereof not been subsequently rescinded, modified or withdrawn in any way, except as may be expressly permitted for the Parent Board by [Section 6.3](#).

(d) The Parent Stockholder Approval obtained through the Parent Stockholders’ Meeting pursuant to [Section 6.4](#) is the only vote of the holders of any class or series of Parent’s shares of capital stock or other securities required in connection with the consummation of the Merger and the other transactions contemplated by this Agreement (including the Parent Stock Issuance and Parent Reverse Split (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application)).

Section 5.5 [No Conflict; Consents and Approvals](#).

(a) The execution, delivery and performance of this Agreement by Parent does not, and the consummation of the Merger and the other transactions contemplated by this Agreement and compliance by Parent with the provisions hereof will not, conflict with, or result in any violation or breach of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of, or result in, termination, cancellation, modification or acceleration of any obligation or to the loss of a benefit under, or result in the creation of any Lien in or upon any of the properties, assets or rights of Parent or any of its Subsidiaries under, or give rise to, any increased, additional, accelerated or guaranteed rights or entitlements under, or require any consent, waiver or approval of any Person pursuant to, any provision of (i) Parent’s Organizational Documents or the Organizational Documents of any Subsidiary of Parent, (ii) any Parent Material Contract or (iii) subject to the governmental filings and other matters referred to in [Section 4.5](#) and [Section 5.5\(b\)](#), any Law or any rule or regulation of Nasdaq applicable to Parent or any of its Subsidiaries, or by which Parent or any of its Subsidiaries, or any of their respective properties or assets, may be bound, except as, in the case of clauses (ii) and (iii), as individually or in the aggregate, would not and would not reasonably be expected to be material to Parent and its Subsidiaries, taken as a whole.

(b) No consent, approval, Order or authorization of, or registration, declaration, filing with or notice to, any Governmental Entity is required by or with respect to Parent or any of its Subsidiaries in connection with the execution, delivery and performance of this Agreement by Parent or the consummation by Parent of the Merger and the other transactions contemplated by this Agreement or compliance with the provisions hereof, except for (i) (x) the filing with the SEC of the Proxy Statement in definitive form, or (y) the filing of with the SEC and the declaration of effectiveness under the Securities Act of the Registration Statement, as the case may be, and the filing with the SEC of such reports under Section 13(a) or 15(d) of the Exchange Act, as may be required in connection with this Agreement and the transactions contemplated by this Agreement, (ii) such other filings and reports as may be required pursuant to the applicable requirements of the Securities Act, the Exchange Act and any other applicable state or federal securities, takeover and “blue sky” Laws, (iii) any filings or approvals required under the rules and regulations of Nasdaq to permit the shares of Parent Common Stock that are to be issued in the Parent Stock Issuance to be listed on Nasdaq, and (iv) such other consents, approvals, Orders, authorizations, registrations, declarations, filings or notices the failure of which to be obtained or made, individually or in the aggregate, would not and would not reasonably be expected to be material to Parent and its Subsidiaries, taken as a whole.

Section 5.6 SEC Reports; Financial Statements.

(a) Parent has filed with or furnished to the SEC on a timely basis true and complete copies of all forms, reports, schedules, statements and other documents required to be filed with or furnished to the SEC by Parent since January 1, 2020 (all such documents, together with all exhibits and schedules to the foregoing materials and all information incorporated therein by reference, the “Parent SEC Documents”), and other than such documents that can be obtained on the SEC’s website at www.sec.gov, Parent has delivered or made available to the Company accurate and complete copies of such Parent SEC Documents. As of their respective filing dates (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), the Parent SEC Documents complied in all material respects with the applicable requirements of the Securities Act, the Exchange Act and the Sarbanes-Oxley Act, as the case may be, including, in each case, the rules and regulations promulgated thereunder, and none of the Parent SEC Documents at the time they were filed (or, if amended or superseded by a subsequent filing prior to the date of this Agreement, as of the date of the last such amendment or superseding filing) contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Parent SEC Documents (collectively, the “Certifications”) are accurate and complete and comply as to form and content with all applicable Laws as of their respective dates.

(b) The financial statements (including the related notes and schedules thereto) included (or incorporated by reference) in the Parent SEC Documents (i) have been prepared in a manner consistent with the books and records of Parent and its Subsidiaries, (ii) have been prepared in accordance with GAAP (except, in the case of unaudited statements, as permitted by Form 10-Q of the SEC) applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto), (iii) comply as to form in all material respects with the published rules and regulations of the SEC applicable thereto, and (iv) present fairly in all material respects the consolidated financial position of Parent and its Subsidiaries as of the dates thereof and their respective consolidated results of operations and cash flows for the periods then ended (except as may be indicated in the notes thereto and subject, in the case of unaudited statements, to normal and recurring year-end audit adjustments that were not, or are not expected to be, material in amount), all in accordance with GAAP and the applicable rules and regulations promulgated by the SEC.

(c) Parent and each of its Subsidiaries maintains a system of internal control over financial reporting designed to provide reasonable assurance that (i) transactions are executed with management's authorization, (ii) transactions are recorded as necessary to permit preparation of the consolidated financial statements in conformity with GAAP and to maintain accountability for the Company's consolidated assets, (iii) access to assets of the Company and its Subsidiaries is permitted only in accordance with management's authorization, and (iv) the reporting of assets of the Company and its Subsidiaries is compared with existing assets at regular intervals.

(d) The books and records of the Company and its Subsidiaries have been, and are being, maintained in all material respects in accordance with GAAP (to the extent applicable) and any other applicable legal and accounting requirements and reflect only actual transactions. Parent has evaluated the effectiveness of Parent's internal control over financial reporting and, to the extent required by applicable Law, presented in any applicable Parent SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation.

(e) Parent has disclosed, based on its most recent evaluation of internal control over financial reporting, to Parent's auditors and the audit committee of the Parent Board (and made available to the Company a summary of the significant aspects of such disclosure) (A) all significant deficiencies and material weaknesses, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Parent's ability to record, process, summarize and report financial information and (B) any fraud, whether or not material, that involves management or other employees who have a significant role in Parent's or its Subsidiaries' internal control over financial reporting. Parent has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Parent's internal control over financial reporting. Since January 1, 2020, there have been no material changes in Parent's internal control over financial reporting.

(f) Neither Parent nor any of its Subsidiaries has extended or maintained credit, arranged for the extension of credit, modified or renewed an extension of credit, in the form of a personal loan or otherwise, to or for any manager or executive officer (or equivalent) of Parent.

(g) Parent maintains “disclosure controls and procedures” (as defined in Rules 13a-15 or 15d-15 under the Exchange Act) reasonably designed to ensure that all information (both financial and non-financial) required to be disclosed by Parent in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that all such information required to be disclosed is accumulated and communicated to the management of Parent, as appropriate, to allow timely decisions regarding required disclosure and to enable the principal executive officer and principal financial officer of Parent to make the certifications required under the Exchange Act with respect to such reports.

(h) Since January 1, 2020, neither Parent nor any of its Subsidiaries nor, to the Knowledge of Parent, any director, officer, or auditor of Parent or any of its Subsidiaries has received or otherwise had or obtained Knowledge of any material complaint, allegation, assertion or claim, whether written or oral, regarding the accounting or auditing practices, procedures, methodologies or methods of Parent or any of its Subsidiaries or their respective internal accounting controls, including any material complaint, allegation, assertion or claim that Parent or any of its Subsidiaries has engaged in questionable accounting or auditing practices.

(i) Neither Parent nor any of its Subsidiaries is a party to, or has any commitment to become a party to, any joint venture, off balance sheet partnership or any similar Contract (including any Contract or arrangement relating to any transaction or relationship between or among Parent and any of its Subsidiaries, on the one hand, and any unconsolidated Affiliate, including any structured finance, special purpose or limited purpose entity or Person, on the other hand, or any “off balance sheet arrangements” (as defined in Item 303(a) of Regulation S-K under the Exchange Act)), where the result, purpose or intended effect of such Contract is to avoid disclosure of any material transaction involving, or material liabilities of, Parent or any of its Subsidiaries in Parent’s or such Subsidiary’s published financial statements or other Parent SEC Documents.

(j) As of the date of this Agreement, there is no consolidated Indebtedness for borrowed money of Parent and its Subsidiaries.

(k) As of the date of this Agreement, Parent is in compliance in all material respects with the applicable provisions of the Sarbanes-Oxley Act and the applicable and current listing and governance rules and regulations of Nasdaq.

(l) Parent has not received any comment letter from the SEC or the staff thereof or any correspondence from Nasdaq or the staff thereof relating to the delisting or maintenance of listing of the Parent Common Stock on Nasdaq. Parent has not disclosed any unresolved comments in the Parent SEC Documents.

(m) Since January 1, 2020, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer, or general counsel of Parent, the Parent Board or any committee thereof, other than ordinary course audits or reviews of accounting policies and practices or internal controls required by the Sarbanes-Oxley Act.

(n) Parent’s auditor has at all times been: (i) a registered public accounting firm (as defined in Section 2(a)(12) of the Sarbanes-Oxley Act); (ii) to the Knowledge of Parent, “independent” with respect to Parent within the meaning of Regulation S-X under the Exchange Act; and (iii) to the Knowledge of Parent, in compliance with subsections (g) through (l) of Section 10A of the Exchange Act and the rules and regulations promulgated by the SEC and the Public Company Accounting Oversight Board thereunder.

Section 5.7 No Undisclosed Liabilities. Neither Parent nor any of its Subsidiaries has any liabilities or obligations of any nature, whether accrued, absolute, contingent or otherwise, known or unknown, whether due or to become due, of a nature that would be required to be recorded or reflected on a balance sheet under GAAP, except (a) to the extent specifically disclosed, reflected, accrued or reserved against in the audited consolidated balance sheet of Parent and its Subsidiaries as at December 31, 2022 included in the Annual Report on Form 10-K filed by Parent with the SEC on March 24, 2023 (without giving effect to any amendment thereto filed on or after the date hereof), (b) incurred in the ordinary course of business consistent with past practice since December 31, 2022 that are not material to Parent and its Subsidiaries, taken as a whole, (c) resulting from performance by Parent or its Subsidiaries required under a Contract made available to the Company prior to the date of this Agreement or entered into after the date of this Agreement in compliance with covenants set forth in Section 6.1(b) (other than as a result of a breach or violation by Parent or its Subsidiaries), or (d) incurred in connection with the transactions contemplated by this Agreement.

Section 5.8 Certain Information. The proxy statement with respect to the Parent Stockholders’ Meeting (as defined below) (such proxy statement, as amended or supplemented from time to time in accordance with this Agreement, the “Proxy Statement”) will not, at the date it is first mailed to the Parent stockholders or at the time of the Parent Stockholders’ Meeting, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they are made, not misleading. The Registration Statement will not, at the time the Registration Statement is filed with the SEC, at the time of any amendment or supplement thereto and at the time the Registration Statement (or any post-effective amendment or supplement) becomes effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they are made, not misleading. Notwithstanding the foregoing, neither Parent nor Merger Sub makes any representation or warranty with respect to statements included or incorporated by reference in the Registration Statement or Proxy Statement based on information supplied in writing by or on behalf of the Company specifically for inclusion or incorporation by reference therein.

Section 5.9 Absence of Certain Changes or Events. Since December 31, 2022 through the date of this Agreement, (a) except in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, Parent and its Subsidiaries have conducted their businesses only in the ordinary course consistent with past practice, (b) there has not been any Parent Material Adverse Effect and (c) none of Parent or any of its Subsidiaries has taken any action, that if taken after the date of this Agreement, would constitute a breach of any covenants set forth in Sections 6.1(b).

Section 5.10 Litigation. There is no Action pending or threatened in writing against or affecting Parent or any of its Subsidiaries, or any of their respective properties or assets, that (a) if adversely determined, individually or in the aggregate, would reasonably be likely to result in material liability to Parent and its Subsidiaries, taken as a whole, or (b) seeks material injunctive or other material non-monetary relief. None of Parent, any of its Subsidiaries, or any of their respective properties or assets, is subject to any material outstanding Order. As of the date of this Agreement, there is no Action pending or threatened in writing seeking to prevent, hinder, modify, delay or challenge the Merger or any of the other transactions contemplated by this Agreement. There are no internal investigations or internal inquiries that, since January 1, 2020, have been conducted or are being conducted by or at the direction of the Parent Board (or any committee thereof) regarding any material accounting practices of Parent or any of its Subsidiaries. For the avoidance of doubt, this Section 5.10 shall not apply to Taxes or the Parent Plans.

Section 5.11 Compliance with Laws. Parent and each of its Subsidiaries are, and since January 1, 2020 have been, in compliance in all material respects with all Laws applicable to their businesses, operations, properties or assets. None of Parent or any of its Subsidiaries has received, since January 1, 2020, a written notice or other written communication alleging or relating to a potential material violation of any Law applicable to their businesses, operations, properties or assets. Parent and each of its Subsidiaries have in effect all material Permits of all Governmental Entities necessary for them to own, lease or operate their properties and assets and to carry on their businesses and operations as now conducted, including, as applicable, all Permits for the development, clinical testing, manufacturing, marketing, distribution and importation or exportation, as currently conducted, of any of its Products or Product candidates. There has occurred no material violation of, default (with or without notice or lapse of time or both) under or event giving to others any right of revocation, non-renewal, adverse modification or cancellation of, with or without notice or lapse of time or both, any such Permit, nor would any such revocation, non-renewal, adverse modification or cancellation result from the consummation of the transactions contemplated by this Agreement. No Action is pending or, to the Knowledge of the Parent, threatened, which seeks to revoke, limit, suspend, or materially modify any Permit.

Section 5.12 Regulatory Matters.

(a) Parent's and its Subsidiaries' Product candidates are being and have been developed, tested, manufactured, packaged, labeled, stored, imported, and exported in compliance in all material respects with all applicable Laws, including, but not limited to Regulatory Laws, as well as any applicable Permits of Parent or any of its Subsidiaries, including but not limited to investigational new drug applications or their national or foreign equivalents. All such Parent Permits are in full force and effect, and to the Knowledge of Parent, no Governmental Entity has threatened to limit, suspend or revoke any Parent Permit.

(b) Neither Parent nor any of its Subsidiaries has (i) received or been subject to any action, notice, citation, suspension, revocation, warning, administrative proceeding or investigation by a Governmental Entity or other Person that alleges or asserts that Parent or any of its Subsidiaries has violated any applicable Regulatory Laws or which requires or seeks any adjustment, modification or alteration in Parent's or any of its Subsidiaries' Product candidates or in the Parent's or any of its Subsidiaries' operations, activities, or services that has not been resolved, including any notice of inspectional observations, FDA warning letter or untitled letter or any similar notices or (ii) been subject to a corporate integrity agreement, deferred prosecution agreement, consent decree, settlement agreement or other similar agreements or Orders mandating or prohibiting future or past activities. Neither Parent nor any of its Subsidiaries has settled, or agreed to settle, any actions brought by any Governmental Entity or any other Person for a violation of any applicable Regulatory Laws, nor is any such action pending resolution. As of the date hereof, (i) there are no restrictions imposed by any Governmental Entity upon the business, activities or services of Parent or any of its Subsidiaries that restrict Parent's or any of its Subsidiaries' business operations, (ii) Parent or any of its Subsidiaries and their respective Product candidates are not, and have not been, otherwise subject to any other enforcement actions taken by the FDA or any other Governmental Entity, and (iii) to the Knowledge of Parent, there are no facts that would reasonably be expected to give rise to such an event as described in the immediately preceding clause (i) or (ii).

(c) Parent and its Subsidiaries have timely filed all material reports, statements, documents, registrations, filings, amendments, supplements and submissions required to be filed by them under applicable Regulatory Laws or the terms of any Parent Permits. Each such filing complied in all material respects with applicable Regulatory Laws as of the date of submission and was true, complete and correct as of the date of submission, and no deficiencies have been asserted in writing by any applicable Governmental Entity with respect to any such filings, submissions, reports or related information. Any material and legally necessary or required updates, changes, corrections, amendments, supplements or modifications to such filings required to be submitted by Parent or any of its Subsidiaries have been submitted thereby to the applicable Governmental Entity or appropriate third party.

(d) All nonclinical studies and clinical trials conducted or sponsored by or on behalf of Parent or any of its Subsidiaries have been, and if still pending are being, conducted in material compliance with applicable research protocols and all applicable Regulatory Laws and Parent Permits, including standards for conducting non-clinical laboratory studies, standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials (including for the protection of the rights and welfare of human subjects), and all applicable Laws restricting the use and disclosure of health information. No nonclinical study or clinical trial conducted or sponsored by or on behalf of Parent or its Subsidiaries with respect to any of Parent's Product candidates has been terminated or suspended prior to completion due to safety or other non-business reasons, and, to the Knowledge of Parent, there are no facts that could give rise to such a determination. No Governmental Entity, institutional review board, ethics committee, independent monitoring committee, or institutional animal care and use committee has provided notice that it has initiated or, to the Knowledge of Parent, is threatening to initiate any action to place a hold order on, or otherwise terminate, delay, suspend or modify any such ongoing nonclinical or clinical testing, and, to the Knowledge of Parent, there are no facts that would reasonably be expected to give rise to such action.

(e) Neither Parent nor any of its Subsidiaries, nor, to the Knowledge of Parent, any officer, employee, or agent of Parent or any of its Subsidiaries (including Persons engaged by Parent for contract research, contract manufacturing, consulting, or other collaboration services), has made an untrue statement of a material fact or a fraudulent statement to the FDA or any other Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or such other Governmental Entity, or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy.

(f) Neither Parent nor its Subsidiaries, nor, to the Knowledge of Parent, any officer, employee, clinical investigator, or agent of Parent or its Subsidiaries has been debarred under 21 U.S.C. § 335a or any similar applicable Law or convicted of any crime or engaged in any conduct for which debarment is mandated or authorized by 21 U.S.C. § 335a or any similar applicable Law. Neither Parent nor any of its Subsidiaries, nor, to the Knowledge of Parent, any officer, employee, clinical investigator, or agent of Parent or any of its Subsidiaries, has been excluded from participation in any federal health care program, or any similar foreign program, or has been convicted of any crime or engaged in any conduct for which such Person would reasonably be expected to be excluded from participating in any federal health care program under Section 1128 of the Social Security Act of 1935, as amended, or any similar applicable Law or program. Neither Parent nor any of its Subsidiaries is, and, to the Knowledge of Parent, no officer, employee, clinical investigator, or agent of Parent or any of its Subsidiaries is subject to an investigation or proceeding by any Governmental Entity that would reasonably be expected to result in any such suspension, exclusion, or debarment, as applicable, and there are no facts, to the Knowledge of Parent, that would reasonably be expected to give rise to such suspension, exclusion, or debarment.

Section 5.13 Benefit Plans.

(a) Section 5.13(a) of the Parent Disclosure Letter contains a true and complete list of each material Parent Plan. For purposes of this Agreement, a “Parent Plan” means each “employee benefit plan” (within the meaning of Section 3(3) of ERISA, whether or not subject to ERISA), “multiemployer plans” (within the meaning of ERISA Section 3(37)), and all pension, retirement, stock purchase, stock option, phantom stock or other equity or equity-based plan, severance, employment, consulting, collective bargaining, change-in-control, retiree medical, retiree dental, retiree vision, retiree life insurance, retention, fringe benefit, bonus, incentive, nonqualified deferred compensation, supplemental retirement, health, life, or disability insurance, dependent care, welfare and all other employee benefit and compensation plans, agreements, programs, policies or other arrangements, whether or not subject to ERISA, whether formal or informal, written or oral, legally binding or not, under which any current or former employee, director or consultant of Parent or any of its Subsidiaries (or any of their dependents) has any present or future right to compensation or benefits, in any case, that Parent, any of its Subsidiaries or any of their respective ERISA Affiliates sponsors or maintains, or is required to sponsor or maintain, is making contributions to or is required to make contributions to or with respect to which Parent or any of its Subsidiaries has any present or future liability or obligation (contingent or otherwise). Parent has provided or made available to the Company a current, accurate and complete copy of each material Parent Plan (including, without limitation, all Parent Equity Plan and the forms of all award agreements evidencing outstanding Parent Stock Awards), or if such Parent Plan is not in written form, a written summary of all of the material terms of such Parent Plan. With respect to each Parent Plan, Parent has furnished or made available to the Company a current, accurate and complete copy of, to the extent applicable: (i) any related trust agreement or other funding instrument, (ii) the most recent determination, opinion or advisory letter of the IRS, (iii) the current summary plan description and summary of material modifications thereto, (iv) for the three most recent years (A) the Form 5500 and attached schedules, (B) audited financial statements, (C) actuarial valuation reports, (D) nondiscrimination testing reports and (v) all correspondences and filings concerning IRS or Department of Labor or other Governmental Entity audits or investigations.

(b) Neither Parent, its Subsidiaries or any of their respective ERISA Affiliates sponsors, maintains, contributes to or is required to sponsor, maintain or contribute to, or has in the past six (6) years sponsored, maintained, contributed to or been required to sponsor, maintain or contribute to, or has any liability (contingent or otherwise) with respect to: (i) a “multiemployer plan” (within the meaning of ERISA Section 3(37)), (ii) a Pension Plan that is subject to Title IV of ERISA or Section 412 of the Code, (iii) a Pension Plan which is a “multiple employer plan” as defined in Section 413 of the Code, (iv) a “funded welfare plan” (within the meaning of Section 419 of the Code) or (v) a “multiple employer welfare arrangement” (within the meaning of Section 3(40) of ERISA).

(c) With respect to the Parent Plans:

(i) each Parent Plan complies in all material respects with its terms and complies in all material respects in form and in operation with the applicable provisions of ERISA and the Code and all other applicable legal requirements;

(ii) each Parent Plan intended to be qualified under Section 401(a) of the Code has received a favorable determination, advisory and/or opinion letter, as applicable, from the IRS that it is so qualified and, to the Knowledge of Parent, nothing has occurred since the date of such letter that would reasonably be expected to result in the loss of the qualified status of such Parent Plan;

(iii) there is no Action (including any investigation, audit or other administrative proceeding) by the Department of Labor, the PBGC, the IRS or any other Governmental Entity or by any plan participant or beneficiary pending, or to the Knowledge of Parent, threatened, relating to the Parent Plans, any fiduciaries thereof with respect to their duties to the Parent Plans or the assets of any of the trusts under any of the Parent Plans (other than non-material routine claims for benefits) and to the Knowledge of the Parent there have been no non-exempt prohibited transactions under Section 406 of ERISA or Section 4975 of the Code that could result in a material Tax or penalty;

(iv) none of the Parent Plans currently provides, or has any liability to provide, post-termination or retiree medical, dental, vision, prescription drug, life insurance or other welfare benefits to any individual for any reason, except as may be required by COBRA, and none of Parent, its Subsidiaries or any of their respective ERISA Affiliates has any liability to provide post-termination or retiree medical, dental, vision, prescription drug, life insurance or other welfare benefits to any individual, except to the extent required by COBRA;

(v) each Parent Plan that is a group health plan under Section 733(a)(1) of ERISA and Section 5000(b)(1) of the Code complies with the ACA, COBRA, and the Health Insurance Portability and Accountability Act of 1996. The Parent has not incurred (whether or not assessed) or is not reasonably expected to incur or be subject to any Tax, penalty or other liability that may be imposed under the ACA or Sections 4980B, 4980D, 4980H, 6721 or 6722 of the Code or with respect to a requirement to timely file ACA information returns with the IRS or provide statements to participants under Section 6056 or 6055 of the Code or state law requirements as applicable, or pursuant to Sections 4976 through 4980 of the Code or Title I of ERISA with respect to any Parent Plans; and

(vi) each Parent Plan is subject exclusively to United States Law.

(d) Each Parent Plan that is a nonqualified deferred compensation plan under Section 409A of the Code has been administered and operated in all material respects in documentary and operational compliance with the provisions of Section 409A of the Code and the regulations thereunder. No Tax penalties or additional Taxes have been imposed or would be reasonably expected to be imposed on any employee or director of Parent or any of its Subsidiaries, and no acceleration of Taxes has occurred or would be reasonably expected to occur with respect to any such employee or director, in each case as a result of a failure to comply with Section 409A of the Code with respect to any Parent Plan that is a “nonqualified deferred compensation plan” within the meaning of Section 409A of the Code.

(e) [Section 5.13\(e\)](#) of the Parent Disclosure Letter contains a true and complete list of each change of control payment, retention payment, severance payment, transaction payment or similar payment that will be treated as a Parent Transaction Related Expense.

(f) Except as set forth on [Section 5.13\(f\)](#) of the Parent Disclosure Letter, neither the execution and delivery of this agreement nor the consummation of the merger will, either alone or in combination with any other event, (A) entitle any Parent Service Provider to any compensation, payment or benefit, (B) accelerate the time of payment or vesting, or increase the amount of or otherwise enhance any compensation or benefit due any such Parent Service Provider, (C) increase any amount of compensation or benefits otherwise payable under any company plan or otherwise or (D) require any contribution or payment to fund any obligation under any Parent plan or otherwise.

Section 5.14 [Labor Matters](#).

(a) Parent and its Subsidiaries are and at all times since January 1, 2020 have been in compliance in all material respects with all applicable Laws relating to labor and employment, including those relating to wages, hours, collective bargaining, unemployment compensation, workers compensation, equal employment opportunity, age and disability discrimination, work authorization and immigration, employee classification, employee privacy, occupational safety and health, payment and withholding of Taxes and COBRA.

(b) Neither Parent nor any of its Subsidiaries is a party to, or otherwise bound by, an effective or pending collective bargaining agreement or similar agreement with a union or labor organization or other person purporting to act as exclusive bargaining representative of any Parent employees, and no employee of Parent or any of its Subsidiaries is covered by any such agreement. To the Knowledge of Parent, there has not been any activity on behalf of any labor union, labor organization or similar employee group to organize any employees of Parent or any of its Subsidiaries. There are, and during the past three (3) years have been, no (i) unfair labor practice charges or complaints against Parent or any of its Subsidiaries pending before the National Labor Relations Board or any other labor relations tribunal or authority, (ii) representation claims or petitions or demands for recognition pending before the National Labor Relations Board or any other labor relations tribunal or authority or (iii) material grievances or pending arbitration proceedings against Parent or any of its Subsidiaries that arose out of or under any collective bargaining agreement, and to the Knowledge of Parent no such charges, complaints, claims, petitions, demands, arbitrations or grievances have been threatened. During the preceding three (3) years, there has not been, and as of the date of this Agreement there is not pending or, to the Knowledge of Parent, threatened, any labor dispute, work stoppage, labor strike or lockout against Parent or any of its Subsidiaries by employees.

(c) To the Knowledge of Parent, no current key employee or officer of Parent or any of its Subsidiaries has notified Parent or any of its Subsidiaries of or expressed any plans to, or is expected to, terminate his or her employment relationship with such entity following the consummation of the transactions contemplated by this Agreement.

(d) Since January 1, 2020, (i) neither Parent nor any Subsidiary has effectuated a “plant closing” (as defined in the WARN Act or any similar state or local law) affecting any site of employment or one or more facilities or operating units within any site of employment or facility, (ii) there has not occurred a “mass layoff” (as defined in the WARN Act) in connection with Parent or any Subsidiary affecting any site of employment or one or more facilities or operating units within any site of employment or facility and (iii) neither Parent nor any Subsidiary has engaged in layoffs or employment terminations sufficient in number to trigger application of any similar state, local or foreign Law. Each Person employed by Parent or any Subsidiary is properly classified as exempt or non-exempt in accordance with applicable overtime Laws, and no Person treated as an independent contractor or consultant by Parent or any Subsidiary should have been properly classified as an employee under applicable law.

(e) Except as set forth on [Section 5.14\(e\)](#) of the Parent Disclosure Letter, there are no Actions against Parent or any of its Subsidiaries pending, or to the Knowledge of Parent, threatened to be brought or filed, in connection with the employment or engagement of any current or former employee, officer, consultant or other service provider of Parent, including, without limitation, any claim relating to employment discrimination, harassment, retaliation, workers’ compensation, occupational safety and health, equal pay, employment classification or any other employment related matter arising under applicable Laws, except where such Action would not, individually or in the aggregate, result in Parent incurring a material liability.

(f) Except as set forth on [Section 5.14\(f\)](#) of the Parent Disclosure Letter or with respect to any Parent Plan (which subject is addressed in [Section 5.13](#) above), the execution of this Agreement and the consummation of the transactions set forth in or contemplated by this Agreement will not result in any breach or violation of, or cause any payment to be made under, any applicable Laws respecting labor and employment or any collective bargaining agreement to which Parent or any of its Subsidiaries is a party.

(g) Except as set forth in Section 5.14(g) of the Parent Disclosure Letter, since January 1, 2020, (i) no written allegations or, to the Knowledge of Parent, verbal allegations of workplace sexual harassment, sexual misconduct, discrimination or retaliation have been made, initiated, filed or, to the Knowledge of Parent, threatened against Parent, any of its Subsidiaries or any of their respective current or former directors, officers or senior level management employees, (ii) to the Knowledge of Parent, no incidents of any workplace sexual harassment, sexual misconduct, discrimination or retaliation have occurred, and (iii) neither Parent nor any of its Subsidiaries have entered into any settlement agreement related to allegations of workplace sexual harassment, sexual misconduct, discrimination or retaliation by any of their directors, officers or employees described in clause (i) hereof or any independent contractor.

Section 5.15 Environmental Matters. Except as, individually or in the aggregate, is not and would not reasonably be expected to be material to Parent and its Subsidiaries, taken as a whole, (i) Parent and each of its Subsidiaries are, and since January 1, 2020 have conducted their respective businesses, in compliance with all, and have not violated any, applicable Environmental Laws; except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to result in a Parent Material Adverse Effect (ii) Parent and its Subsidiaries have obtained all Environmental Permits, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to result in a Parent Material Adverse Effect, and there has occurred no violation of or default under any such Environmental Permit giving to others any right of revocation, non-renewal, adverse modification or cancellation of any such Environmental Permit, nor, to the Knowledge of Parent, would any such revocation, non-renewal, adverse modification or cancellation result from the consummation of the Merger or any other transactions contemplated by this Agreement; (iii) to the Knowledge of Parent, there has been no Release of, or exposure of any Person to, any Hazardous Substance by Parent or any of its Subsidiaries or, to the Knowledge of Parent, any other Person in any manner that has given or would reasonably be expected to give rise to any remedial or investigative obligation, corrective action requirement or liability of Parent or any of its Subsidiaries under applicable Environmental Laws; (iv) neither Parent nor any of its Subsidiaries has received any written claims, notices, demand letters or requests for information (except for such claims, notices, demand letters or requests for information the subject matter of which has been resolved prior to the date of this Agreement) from any Governmental Entity or any other Person asserting that Parent or any of its Subsidiaries is in violation of, or has known, alleged or potential liability under, any Environmental Law; (v) to the Knowledge of Parent no Hazardous Substance has been disposed of, arranged to be disposed of, Released or transported by or on behalf of Parent or any of its Subsidiaries in violation of any applicable Environmental Law, or in a manner that has given rise to, or that would reasonably be expected to give rise to, any liability under any Environmental Law, in each case, on, at, under or from any current properties or facilities owned, leased or operated by Parent or any of its Subsidiaries or, to the Knowledge of Parent, as a result of any operations or activities of Parent or any of its Subsidiaries at any other location. To the extent applicable, Parent has made available to the Company copies of all material environmental documents (including reports of assessments, audits, investigations or sampling, notices of violation, and Environmental Permits) in Parent's possession or reasonable control with respect to actual or potential liability pursuant to applicable Environmental Law.

Section 5.16 Taxes.

(a) Parent and each of its Subsidiaries have timely (i) filed all material Tax Returns required to be filed by any of them and all material Tax Returns filed by, or on behalf of, Parent and its Subsidiaries are true, accurate and complete in all material respects; and (ii) paid in full (or caused to be timely paid in full) all material Taxes that are required to be paid by or with respect to them, whether or not such Taxes were shown as due on such Tax Returns.

(b) All material Taxes not yet due and payable by Parent and its Subsidiaries as of the date of the latest Parent SEC Documents have been, in all respects, properly accrued in accordance with GAAP on the most recent financial statements contained in the Parent SEC Documents. Since the date of such financial statements, Parent and each of its Subsidiaries have not incurred, individually or in the aggregate, any liability for material Taxes outside the ordinary course of business consistent with past practice.

(c) Neither Parent nor any of its Subsidiaries has executed any waiver of any statute of limitations on, or extended the period for the assessment or collection of, any amount of Tax, in each case that has not since expired.

(d) No Tax Actions with respect to material Taxes or any material Tax Return of Parent or any of its Subsidiaries are presently in progress or have been asserted, threatened or proposed in writing. No deficiencies or claims for material Taxes have been claimed, proposed, assessed or asserted in writing against Parent or any of its Subsidiaries by a Governmental Entity, other than any such claim, proposal, assessment or assertion that has been satisfied by payment in full, settled or withdrawn.

(e) Parent and each of its Subsidiaries have timely withheld all material Taxes required to have been withheld from payments made (or deemed made) to its employees, independent contractors, creditors, equityholders and other third parties and, to the extent required, such Taxes have been timely paid to the relevant Governmental Entity.

(f) Neither Parent nor any of its Subsidiaries has engaged in a “listed transaction” as set forth in Treasury Regulation § 1.6011-4(b)(2).

(g) Neither Parent nor any of its Subsidiaries (i) is a party to or bound by, or currently has any liability pursuant to, any Tax sharing, allocation or indemnification agreement or obligation, other than any such agreement or obligation entered into in the ordinary course of business the primary purpose of which is unrelated to Taxes; (ii) is, or has been, a member of a group (other than a group the common parent of which is Parent or one of Parent’s Subsidiaries) filing a consolidated, combined, affiliated, unitary or similar income Tax Return; (iii) has any liability for the Taxes of any Person (other than Parent and its Subsidiaries) pursuant to Treasury Regulation § 1.1502-6 (or any similar provision of state, local or non-United States Law) as a transferee or successor, or otherwise by operation of Law; or (iv) is, or has been, treated as a resident for any income Tax purpose, or as subject to Tax by virtue of having a permanent establishment, an office or fixed place of business, in any country other than the country in which it was or is organized.

(h) No private letter rulings, technical advice memoranda, or similar agreements or rulings have been requested, entered into or issued by any taxing authority with respect to Parent or any of its Subsidiaries which rulings remain in effect.

(i) Neither Parent nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of (i) a change in, or use of improper, method of accounting requested or initiated on or prior to the Closing Date, (ii) a “closing agreement” as described in Section 7121 of the Code (or any similar provision of Law) executed on or prior to the Closing Date, (iii) an installment sale or open transaction disposition made on or prior to the Closing Date, (iv) any prepaid amount received or deferred revenue accrued on or prior to the Closing Date, (v) any income earned as a result of transactions or events occurring in a taxable period (or portion thereof) ending on or prior to the Closing Date that would result in an inclusion under Section 951(a) or Section 951A of the Code, or (vi) an election under Section 965 of the Code.

(j) There are no Liens for Taxes upon any of the assets of Parent or any of its Subsidiaries other than Permitted Liens.

(k) None of Parent or any of its Subsidiaries has distributed stock of another Person or has had its stock distributed by another Person in the three (3) year period ending prior to the Closing, in a transaction that was purported or intended to be governed in whole or in part by Sections 355 or 361 of the Code.

(l) Parent and each of its Subsidiaries have conducted all intercompany transactions, and maintained all related documentation, in compliance with Section 482 of the Code (or any similar provision of applicable Law).

(m) Neither Parent nor any of its Subsidiaries knows of any fact, agreement, plan or other circumstance that could reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment .

(n) No claim has been made in writing by any Governmental Entity in a jurisdiction where neither Parent nor any of its Subsidiaries currently files, or has filed, a Tax Return that Parent or any of its Subsidiaries is, or may be, subject to taxation by such jurisdiction.

(o) No Subsidiary of Parent is a “passive foreign investment company” within the meaning of Section 1297 of the Code.

(p) Neither Parent nor any of its Subsidiaries has engaged in a trade or business, had a permanent establishment (within the meaning of an applicable Tax treaty or convention), or otherwise been subject to taxation in any country other than the country of its formation.

(q) Neither Parent nor any of its Subsidiaries is a party to any joint venture, partnership, or other arrangement that is treated as a partnership for federal or foreign income Tax purposes.

(r) Parent is and has been since its formation properly treated as a “C corporation” for U.S. federal and applicable state tax purposes. The U.S. federal income tax classification of each Subsidiary of Parent is set forth on [Schedule 5.16\(r\)](#).

For purposes of this [Section 5.16](#), where the context permits, each reference to Parent and its Subsidiaries shall include a reference to any Person for whose Taxes Parent or its Subsidiaries are liable under applicable Law.

Section 5.17 [Contracts](#).

(a) [Section 5.17\(a\)](#) of the Parent Disclosure Letter identifies each Contract to which Parent or any of its Subsidiaries is a party, or by which Parent or any of its Subsidiaries is bound, that constitutes a Parent Material Contract as of the date of this Agreement. For purposes of this Agreement, each of the following to which Parent or any of its Subsidiaries is a party or by which it is bound as of the date of this Agreement constitutes a “[Parent Material Contract](#)”:

(i) any Contract that is a settlement, conciliation or similar agreement with or approved by any Governmental Entity and pursuant to which (A) Parent or any of its Subsidiaries will be required after the date of this Agreement to pay any monetary obligations or (B) that contains material obligations or limitations on the conduct of Parent or its Subsidiaries;

(ii) any Contract (A) by its terms limiting the freedom or right of Parent or any of its Subsidiaries or Affiliates to engage in any line of business or to compete with any other Person in any location or line of business, (B) containing any “most favored nations” terms and conditions (including with respect to pricing) granted by Parent or any of its Subsidiaries, or (C) containing exclusivity obligations or otherwise limiting the freedom or right of Parent or any of its Subsidiaries or Affiliates to sell, distribute or manufacture any products or services for any other Person;

(iii) any Contract that requires by its terms or is reasonably expected to require the payment or delivery of cash or other consideration to Parent or any of its Subsidiaries in an amount having an expected value in excess of \$100,000 in the fiscal year ending December 31, 2023 or by Parent or any of its Subsidiaries in an amount having an expected value in excess of \$100,000 in the fiscal year ending December 31, 2023 and in each case which cannot be cancelled by Parent or its Subsidiaries without penalty or further payment without more than ninety (90) days’ notice;

(iv) any Contract relating to Indebtedness for borrowed money in excess of \$100,000 (whether incurred, assumed, guaranteed or secured by any asset) of Parent or any of its Subsidiaries or creating any material Liens with respect to any assets of Parent or any of its Subsidiaries;

(v) any Contract with any Person constituting a joint venture, collaboration, partnership or similar profit sharing arrangement or requiring any Person to develop or commercialize any product, technology or service;

(vi) any Contract (excluding any Parent Plan) that by its express terms requires Parent or any of its Subsidiaries, or any successor to, or acquirer of, Parent or any of its Subsidiaries, to make any payment to another Person as a result of a change of control of Parent or any of its Subsidiaries, as applicable (a "Parent Change of Control Payment") or gives another Person a right to receive or elect to receive a Parent Change of Control Payment;

(vii) any Contract that prohibits the declaration or payment of dividends or distributions in respect of the limited liability company interests, capital stock or other equity interests of Parent or its Subsidiaries, the pledging of the limited liability company interests, capital stock or other equity interests of Parent or its Subsidiaries or the issuance of any guaranty by Parent or any of its Subsidiaries;

(viii) any material (A) in-bound license (other than Commercially Available Software) and (B) out-bound license of Intellectual Property Rights (other than non-exclusive licenses granted by Parent or any of its Subsidiaries in the ordinary course of business);

(ix) any Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of \$100,000 pursuant to its express terms;

(x) any Contract relating to the disposition or acquisition of assets or rights (including equity interests) except for sales of inventory in the ordinary course of business;

(xi) any Contract pursuant to which Parent or any of its Subsidiaries leases or subleases any material real property;

(xii) any Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to the Parent in connection with this Agreement and the transactions contemplated hereby;

(xiii) any Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of the Parent or any of its Subsidiaries; or

(xiv) any Contract requiring payment by or to the Parent or any of its Subsidiaries after the date of this Agreement in excess of \$100,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Parent or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, collaboration, development or other agreement currently in force under which the Parent or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which the Parent or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Parent or any of its Subsidiaries; or (D) license granted to any third party to manufacture or produce any product, service or technology of the Parent or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of the Parent or any of its Subsidiaries, in each case, except for Contracts entered into in the ordinary course of business consistent with past practice;

(xv) any Contract granting a right of first refusal, right of first offer, or similar right with respect to any assets of a Person or that contains any provision requiring the purchase of all or a material portion of requirements for a given product or service from another Person; or

(xvi) any other Contract that is currently in effect and is required to be filed by Parent as an exhibit pursuant to Item 601(b)(10) of Regulation S-K under the Securities Act or that would be required to be disclosed under Item 404 of Regulation S-K under the Securities Act.

(b) (i) Each Parent Material Contract is valid and binding on Parent and any of its Subsidiaries to the extent such Subsidiary is a party thereto, as applicable, and to the Knowledge of Parent, each other party thereto, and is in full force and effect and enforceable in accordance with its terms, subject to the Enforceability Exceptions;(ii) Parent and each of its Subsidiaries, and, to the Knowledge of Parent, each other party thereto, has performed all material obligations required to be performed by it under each Parent Material Contract; and (iii) there is no material default under any Parent Material Contract by Parent or any of its Subsidiaries or, to the Knowledge of Parent, any other party thereto, and to Parent's Knowledge, no event or condition has occurred that constitutes, or, after notice or lapse of time or both, would constitute, a material default on the part of Parent or any of its Subsidiaries or, to the Knowledge of Parent, any other party thereto under any such Parent Material Contract, nor has Parent or any of its Subsidiaries received any written notice of any such material default, event or condition. Parent has furnished or made available to the Company true and complete copies of all Parent Material Contracts, including all amendments thereto.

Section 5.18 Insurance. Parent and each of its Subsidiaries is covered by valid and currently effective insurance policies issued in favor of Parent or one or more of its Subsidiaries that are customary and adequate for companies of similar size in the industries and locations in which Parent operates. Section 5.18 of the Parent Disclosure Letter sets forth, as of the date hereof, a true and complete list of all material insurance policies issued in favor of Parent or any of its Subsidiaries, or pursuant to which Parent or any of its Subsidiaries is a named insured or otherwise a beneficiary, as well as any historic occurrence-based policies still in force. With respect to each such insurance policy, (a) such policy is in full force and effect and all premiums due thereon have been paid and (b) neither Parent nor any of its Subsidiaries is in breach or default, and has not taken any action or failed to take any action which (with or without notice or lapse of time, or both) would constitute such a breach or default, or would permit termination or modification of, any such policy. Other than customary end of policy notifications from insurance carriers, since January 1, 2020, no notice of cancellation or termination have been received with respect to any such policy. This Section 5.18 shall not apply to insurance relative to any Parent Plan.

Section 5.19 Properties.

(a) Parent or one of its Subsidiaries has good and valid title to, or in the case of leased property and leased tangible assets and properties, a valid leasehold interest in, all of its real properties and tangible assets and properties that are necessary for Parent and its Subsidiaries to conduct their respective businesses as currently conducted, free and clear of all Liens other than Permitted Liens of Parent and its Subsidiaries, and the material tangible personal property currently used in the operation of the business of Parent and its Subsidiaries is in good working order (reasonable wear and tear excepted).

(b) Each of Parent and its Subsidiaries has complied with the terms of all real property leases to which it is a party (the "Parent Real Property Leases"), and all such leases are in full force and effect, except for any such noncompliance or failure to be in full force and effect that, individually or in the aggregate, has not had and would not reasonably be expected to have a Parent Material Adverse Effect. Each of Parent and its Subsidiaries enjoys peaceful and undisturbed possession under all such leases, except for any such failure to do so that, individually or in the aggregate, has not had and would not reasonably be expected to have a Parent Material Adverse Effect.

(c) Section 5.19(c) of the Parent Disclosure Letter sets forth a true and complete list of (i) all real property owned by Parent or any of its Subsidiaries and (ii) all Parent Real Property Leases.

(d) This Section 5.19 does not relate to Intellectual Property matters, which matters are the subject of Section 5.20.

Section 5.20 Intellectual Property; Data Privacy.

(a) Section 5.20(a) of the Parent Disclosure Letter sets forth a true and complete list of all (i) patents and patent applications; (ii) trademark registrations and applications; (iii) copyright registrations and applications; (iv) domain names, in each case, owned or purported to be owned by Parent or any of its Subsidiaries ((i)-(iv) collectively, "Parent Registered IP"), indicating for each, (a) the name (or names for co-applicants/registrants/owners) of applicant/registrant and current owner, (b) the applicable jurisdiction, registration number (or application number), (c) the date issued (and date filed) and (d) the status (including the next action or payment and date due); and (v) a true and complete list of all unregistered Trademarks owned or purported to be owned by the Parent or any of its Subsidiaries that is material to the business. (A) All of the Parent Registered IP is subsisting and, to the Knowledge of Parent, valid and enforceable, in the case of any Parent Registered IP that is registered or issued, (B) no Parent Registered IP is involved in any interference, reissue, derivation, opposition, cancellation or similar Action and, to the Knowledge of Parent, no such Action is threatened with respect to any of the Parent Registered IP and (C) except as set forth on Section 5.20(a) of the Parent Disclosure Letter, Parent or its Subsidiaries own exclusively, free and clear of any and all Liens (other than Permitted Liens of Parent and its Subsidiaries), all Parent Owned IP. All Parent Registered IP is in compliance in all material respects with all legal requirements (including the timely filing of responses, statements or affidavits of use and incontestability and renewal applications and required fees with respect to Trademarks and the payment of filing, examination, maintenance and other fees and the filing of responses, declarations and affidavits and compliance with any duty of disclosure with respect to Patents), have not been adjudged to be invalid or unenforceable in whole or in part, and are not subject to any fees, responses or actions falling due within ninety (90) days after the Closing Date.

(b) Parent and its Subsidiaries have taken commercially reasonable measures to maintain the confidentiality of all information that constitutes or constituted a material Trade Secret of Parent or its Subsidiaries, including requiring all Persons having access thereto to execute written non-disclosure agreements or other binding obligations to maintain confidentiality of such information. There has been no unauthorized disclosure to any third party of any material confidential information or Trade Secrets owned by Parent or its Subsidiaries, except where such disclosure was permitted by Law. All of the material Parent Owned IP has been created by employees of the Parent or its Subsidiaries within the scope of their employment or by independent contractors of the Parent or its Subsidiaries or other Persons providing services to the Parent or its Subsidiaries who have executed contracts that expressly and irrevocably assign, using present tense assignment language, all right, title, and interest in such Parent Owned IP on a worldwide, royalty-free basis. To the Knowledge of Parent, no current or former employee, consultant, contractor, or potential partner or investor of the Parent or its Subsidiaries is in unauthorized possession of any of the material confidential information, Trade Secrets or software included in the Parent Owned IP. To the Knowledge of Parent, no current or former independent contractor engaged by the Parent or its Subsidiaries or other Person that has provided services to the Parent or its Subsidiaries (x) created any Parent Owned IP using the equipment, supplies, facilities, confidential information or Intellectual Property of, or in the course of work for, any other employer of or Person engaging the services of such independent contractor or such other Person that has provided services to the Parent or its Subsidiaries where such use would affect the Parent's or its Subsidiaries' rights in such Parent Owned IP or (y) in providing such services, violated any agreement between such independent contractor or such other Person and any other employer of or Person engaging the services of such independent contractor or such other Person.

(c) (i) All material Parent Owned IP is free and clear of any covenants not to sue, encumbrances, joint ownership obligations or duties, or Action (other than (A) those occurring in the ordinary course of seeking and maintaining patents and other registrations of Intellectual Property, (B) Permitted Liens and (C) out-bound license of Intellectual Property Rights listed in Section 4.17(a)(viii)(B)), (ii) to the Knowledge of Parent, the conduct of the businesses of Parent and its Subsidiaries has not in the past six (6) years infringed, misappropriated or diluted, and does not infringe, misappropriate or dilute, any Intellectual Property of any Person, (iii) in the past six (6) years, neither Parent nor any of its Subsidiaries has received any written notice or claim asserting or suggesting that any such infringement, misappropriation, or dilution is, or may be, occurring or has, or may have, occurred, (iv) to the Knowledge of Parent, no Person is infringing, misappropriating, or diluting in any material respect any Parent Owned IP, and (v) in the past six (6) years, neither Parent nor its Subsidiaries has threatened to bring, and neither Parent nor its Subsidiaries has brought, any Action regarding the ownership, use, validity or enforceability of any Parent Owned IP. Except as set forth on [Section 5.20\(c\)](#) of the Parent Disclosure Letter, to the Knowledge of Parent, no Abbreviated New Drug Application referencing any Product of Parent or any of its Subsidiaries has been submitted to the FDA.

(d) Parent Software. All software included in Parent Owned IP that is material to the business of Parent and its Subsidiaries (“Parent Software”) and, to the Knowledge of Parent, all software licensed from third parties that is material to the business of Parent and its Subsidiaries, is free from any significant defect or significant programming or documentation error, operates and runs in a reasonable and efficient business manner, conforms in all material respects to the specifications thereof, if applicable, and, with respect to the Parent Software, Parent or its Subsidiaries possess or have rights to use, as applicable, the source code, system documentation, statements of principles of operation and schematics, as well as any pertinent commentary, explanation, program (including compilers), workbenches, tools and higher level (or “proprietary”) language used for the development, maintenance, and implementation thereof, so that a trained computer programmer could reasonably be expected to maintain, support, compile and deploy the same, except in each case where such defect or error, or failure to operate or run, failure to conform, or failure to possess or have such rights would not have a Parent Material Adverse Effect. No ownership rights in the Parent Software have been transferred to any third party. Parent or its Subsidiaries is the sole and exclusive owner of the entire and unencumbered right, title, and interest in the Parent Software created by Parent or its Subsidiaries. Parent or its Subsidiaries has the right to use all software development tools, library functions, compilers, and other third party software that are currently used in the operation and/or modification of the Parent Software. Parent and its Subsidiaries have used commercially reasonable efforts to prevent the introduction into the Parent Software and software licensed from third parties, and such Parent Software does not contain, any unauthorized “back door,” “drop dead device,” “time bomb,” “Trojan horse,” “virus” or “worm” (as such terms are commonly understood in the software industry) or any other unauthorized code designed or intended to have any of the following functions: disrupting or disabling the operation of, or providing unauthorized access to, a computer system or network or other device on which such code is stored or installed.

(e) (i) Parent and its Subsidiaries have taken commercially reasonable steps to protect the confidentiality and security of the computer and information technology systems used by Parent and its Subsidiaries (the “Parent IT Systems”) and the information and transactions stored or contained therein or transmitted thereby, (ii) to the Knowledge of Parent, since January 1, 2020, there has been no unauthorized, unlawful, accidental or improper use, loss, destruction, disclosure, access, transmittal, modification, acquisition, unavailability, compromise or corruption of any information or data (including, without limitation, Personal Information and confidential information) stored, maintained or otherwise Processed (a “Security Incident”) by Parent and its Subsidiaries and (iii) since January 1, 2020, there have been no material failures, crashes, viruses, or actual or reasonably suspected Security Incidents affecting the Parent IT Systems. The Parent IT Systems function in accordance with their specifications without material defects or errors when used in accordance with such specifications and related documentation. Parent and its Subsidiaries have taken reasonable precautions to protect the confidentiality, integrity and security of the Parent IT Systems and all data and information stored or contained therein or transmitted thereby, including exercising reasonable care and due diligence in selecting third party service providers to host, maintain and protect Parent IT Systems and to provide commercially reasonable business continuity and disaster recovery services. Since January 1, 2020, there has been no continued substandard performance of any Parent IT Systems which has caused the substantial disruption or interruption in or to the use of the Parent IT Systems or the operation of the business of Parent and its Subsidiaries. The Parent IT Systems are in good working condition and are sufficient for the operation of the business of Parent and its Subsidiaries as currently conducted.

(f) Since January 1, 2020, the Parent and its Subsidiaries have at all times complied in all material respects with all applicable Privacy Commitments. Neither this Agreement nor the consummation of the transactions contemplated by this Agreement will materially breach any Privacy Laws.

(g) The Parent and its Subsidiaries have established and maintain, and/or have exercised reasonable care and due diligence in selecting third party service providers to establish and maintain, commercially reasonable technical, physical and organizational measures designed to protect Company Data collected, used or held for use by the Parent or its Subsidiaries, or to which the Parent or its Subsidiaries have access or otherwise Process, against loss and unauthorized access, use, modification, disclosure, Processing or other misuse.

(h) Since January 1, 2020, neither the Parent nor any of its Subsidiaries have experienced any material Data Security Breach.

(i) Neither the Parent nor any of its Subsidiaries has received any written Order, request, warning, reprimand, inquiry, notification, allegation, or claim alleging that it is in violation of or has not complied, in any material respect, with any Privacy Commitment. Neither the Parent nor any of its Subsidiaries has receive been notified that it is currently and neither the Parent nor any of its Subsidiaries have previously been notified that they are under investigation, or subject to any complaint, audit, proceeding, investigation, enforcement action, inquiry or claim, initiated by any (a) Governmental Entity, (b) state, federal or foreign self-regulating body, or (c) any Person, regarding or alleging that the Processing of Personal Information by the Parent or any of its Subsidiaries is in violation of any Privacy Commitment. No Person has claimed or, to the Knowledge of the Parent or any of its Subsidiaries, threatened to claim, any material amount of compensation (or an offer for compensation) from the Parent or any of its Subsidiaries under or in connection with any actual or alleged violation of any Privacy Commitment.

(j) To the Knowledge of Parent, no government funding, facilities or resources of a university, college, other educational institution or research center or funding from third parties was used in the development of the Parent Owned IP, or to the Knowledge of Parent, exclusively licensed to Parent, and no Governmental Entity, university, college, other educational institution or research center has, to the Knowledge of Parent, any claim or right in or to such Intellectual Property.

(k) Except as set forth on [Section 5.20\(k\)](#) of the Parent Disclosure Letter, the execution, delivery and performance by Parent of this Agreement, and the consummation of the transactions contemplated by this Agreement, will not result in the loss of, or give rise to, any right of any Third Person to terminate or modify any of Parent's or any Subsidiaries' rights or obligations under any agreement under which Parent or any of its Subsidiaries grants to any Person, or any Person grants to Parent or any of its Subsidiaries, a license or right under or with respect to any Intellectual Property that is material to any of the businesses of Parent or any of its Subsidiaries.

Section 5.21 [Takeover Laws](#). The Parent Board has taken and will take all actions so that the restrictions applicable to business combinations contained in Section 203 of the DGCL with respect to Parent are, and will be, inapplicable to the execution, delivery and performance of this Agreement and the timely consummation of the Merger and the other transactions contemplated by this Agreement. No other Takeover Laws or any similar anti-takeover provision in Parent's Organizational Documents is, or at the Effective Time will be, applicable to this Agreement, the Merger or any of the other transactions contemplated by this Agreement.

Section 5.22 [Related Party Transactions](#). Since January 1, 2020 through the date of this Agreement, except with respect to any Parent Plans, there have been no transactions, agreements, arrangements or understandings between Parent or any of its Subsidiaries, on the one hand, and the Affiliates of Parent, on the other hand (other than Parent's Subsidiaries) that would be required to be disclosed under Item 404 of Regulation S-K under the Securities Act and that have not been so disclosed in the Parent SEC Documents.

Section 5.23 [Certain Payments](#). Neither Parent nor any of its Subsidiaries (nor, to the Knowledge of Parent, any of their respective directors, executives, representatives, agents or employees) (a) has used or is using any corporate funds for any illegal contributions, gifts, entertainment or other unlawful expenses relating to political activity, (b) has used or is using any corporate funds for any direct or indirect unlawful payments to any foreign or domestic governmental officials or employees, (c) has violated, or is violating, any provision of the Foreign Corrupt Practices Act of 1977, (d) has established or maintained, or is maintaining, any unlawful fund of corporate monies or other properties or (e) has made any bribe, unlawful rebate, payoff, influence payment, kickback or other unlawful payment of any nature.

Section 5.24 Brokers. No broker, investment banker, financial advisor or other Person, other than Canaccord Genuity LLC, the fees and expenses of which will be paid by Parent, is entitled to any broker's, finder's, financial advisor's, opinion, success, transaction or other similar fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Parent.

Section 5.25 Opinion of Financial Advisor. Parent has received the opinion of Canaccord Genuity LLC, dated the date of this Agreement, to the effect that, as of such date and based upon and subject to the qualifications, limitations, assumptions and other matters set forth therein, the Exchange Ratio is fair, from a financial point of view, to Parent.

Section 5.26 Merger Sub.

Merger Sub was formed solely for the purpose of engaging in the Merger and the other transactions contemplated by this Agreement, and Merger Sub has not engaged in any business other than in connection with the transactions contemplated by this Agreement.

Section 5.27 No Other Representations or Warranties. Except for the representations and warranties set forth in Article IV (as qualified by the Company Disclosure Letter) and any certificate delivered by the Company pursuant to Section 7.2(c), Parent acknowledges and agrees that none of the Company, its Subsidiaries or any other Person on behalf of the Company or any of its Subsidiaries makes any other express or implied representation or warranty, express or implied, at law or in equity, with respect to any of it or any of its assets, liabilities or operations, and any such other representations or warranties are expressly disclaimed, and Parent has not relied on any such information or any representation or warranty not set forth in Article IV (as qualified by the Company Disclosure Letter) or any certificate delivered by the Company pursuant to Section 7.2(c).

ARTICLE VI COVENANTS

Section 6.1 Conduct of Business.

(a) Conduct of Business by the Company. During the period from the date of this Agreement to the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, except (i) as consented to in writing in advance by Parent, (ii) as otherwise specifically required by this Agreement, (iii) as set forth in Section 6.1(a) of the Company Disclosure Letter, or (iv) as required by applicable Law, the Company shall, and shall cause each of its Subsidiaries to, carry on its business in the ordinary course consistent with past practice and use commercially reasonable efforts to preserve intact its business organization, preserve its material assets, rights and properties in good repair and condition and preserve its goodwill and maintain satisfactory relationships with customers, suppliers, licensors, licensees, distributors and others having business dealings with it and in compliance in all material respects with applicable Law, and shall continue to pay outstanding accounts payable and other current liabilities (including payroll) when due in payable). In addition to and without limiting the generality of the foregoing, during the period from the date of this Agreement to the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, except as (x) specifically required by this Agreement, as required by applicable Law or (y) as set forth in Section 6.1(a) of the Company Disclosure Letter, the Company shall not, and shall not permit any of its Subsidiaries, without Parent's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), to:

(i) (A) declare, set aside or pay any dividends on, or make any other distributions (whether in cash, equity interests or property) in respect of, any of the shares of capital stock or other equity interests, except for dividends by a wholly owned Subsidiary of the Company to its parent, (B) purchase, redeem or otherwise acquire units of shares of capital stock or other equity interests of the Company or its Subsidiaries or grant any options, warrants, or rights to acquire any such shares of capital stock or other equity interests (except for withholding Taxes upon exercise of Company Options or Company Warrants, in each case outstanding on the Measurement Date (to the extent issued in accordance with their terms as in effect on the Measurement Date)), or (C) split, combine, reclassify or otherwise amend the terms of any of its shares of capital stock or other equity interests or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or other equity interests (other than the repurchase of shares of Company Common Stock from terminated employees, directors or consultants or the issuance of shares of Company Common Stock issued upon the exercise of Company Options or Company Warrants or the conversion of Company Preferred Stock or Company Convertible Notes, in each case outstanding on the Measurement Date (to the extent issued in accordance with their terms as in effect on the Measurement Date));

(ii) issue, deliver, sell, grant, pledge or otherwise encumber or subject to any Lien (other than Permitted Liens) any shares of its capital stock or other equity interests or any securities convertible into, or exchangeable for or exercisable for any such shares of capital stock or other equity interests, or any rights, warrants or options to acquire, any such shares of capital stock or other equity interests, or any stock appreciation rights, "phantom" stock rights, performance units, rights to receive shares of capital stock of the Company on a deferred basis or other rights linked to the value of shares of Company Capital Stock, including pursuant to Contracts as in effect on the date hereof (other than the issuance of shares of Company Common Stock issued upon the exercise of Company Options or Company Warrants or the conversion of Company Preferred Stock or Company Convertible Notes, in each case outstanding on the Measurement Date (to the extent issued in accordance with their terms as in effect on the Measurement Date));

(iii) amend or otherwise change, or authorize the amendment or change of, the Company's Organizational Documents (whether by merger, consolidation or otherwise);

(iv) form any Subsidiary or directly or indirectly acquire or agree to acquire (A) by merging or consolidating with, purchasing a substantial equity interest in or a substantial portion of the assets of, making an investment in or loan or capital contribution to or in any other manner, any corporation, partnership, association or other business organization or division thereof or (B) any assets that are otherwise material to the Company and its Subsidiaries, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the transactions contemplated by this Agreement;

(v) directly or indirectly sell, lease, license, sell and leaseback, abandon, mortgage or otherwise encumber or subject to any Lien (other than a Permitted Lien) or otherwise dispose in whole or in part of any of its material properties, assets or rights or any interest therein (including any Company Owned IP), except the granting of non-exclusive licenses of Intellectual Property in the ordinary course of business consistent with past practice, the abandonment of Intellectual Property in the exercise of the good faith business judgment of the Company and the expiration of Intellectual Property in accordance with the applicable statutory term to the extent not extendable;

(vi) adopt or enter into a plan of complete or partial liquidation, dissolution, restructuring, recapitalization or other reorganization;

(vii) (A) incur, create, assume or otherwise become liable for, or repay or prepay, any Indebtedness for borrowed money, or amend, modify or refinance any Indebtedness of borrowed money, or (B) make any loans, advances or capital contributions to, or investments in, any other Person, other than the Company or any direct or indirect wholly owned Subsidiary of the Company;

(viii) incur or commit to incur any capital expenditure or authorization or commitment with respect thereto that in the aggregate are in excess of \$100,000;

(ix) (A) pay, discharge, settle or satisfy any claims, liabilities or obligations (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than the payment, discharge or satisfaction in the ordinary course of business consistent with past practice or as required by their terms in effect on the date of this Agreement of claims, liabilities or obligations incurred since the date of the financial statements in the ordinary course of business consistent with past practice, (B) cancel any material Indebtedness owed to the Company or any of its Subsidiaries or (C) waive, release, grant or transfer any right of material value;

(x) (A) materially modify, materially amend, terminate, cancel or extend any Company Material Contract or (B) other than in the ordinary course of business consistent with past practice, enter into any Contract that if in effect on the date hereof would be a Company Material Contract;

(xi) except with respect to an Action to enforce its rights under this Agreement, commence any Action, compromise, settle or agree to settle any Action (including any Action relating to this Agreement or the transactions contemplated by this Agreement) other than compromises, settlements or agreements in the ordinary course of business consistent with past practice that involve only the payment of money damages not in excess of \$50,000 individually or \$100,000 in the aggregate, in any case without the imposition of any equitable relief on, or the admission of wrongdoing by, the Company or any of its Subsidiaries; provided, however, that this clause (xi) shall not apply to any Action the defense of which is under the control of any insurer of the Company or any of its Subsidiaries;

(xii) change its financial or tax accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or applicable Law, or revalue any of its material assets;

(xiii) make any change in the policies of the Company or any of its Subsidiaries as in effect on the date of this Agreement with respect to cash management practices, including the payment of accounts payable or accrued expenses or the collection of accounts receivable or other receivables, or otherwise make any change with respect to the management of working capital;

(xiv) settle or compromise any material liability for Taxes; file any amended Tax Return or surrender any claim for a Tax refund; make, revoke or modify any entity classification or other material Tax election; file any Tax Return other than on a basis consistent with past practice; consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of Taxes; grant any power of attorney with respect to Taxes; or enter into any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, Tax holiday or any closing or other similar agreement (other than an agreement entered into in the ordinary course of business, the primary purpose of which is not related to Taxes), or change any method of accounting for Tax purposes;

(xv) change its fiscal year;

(xvi) except as required by the terms of any Company Plan as in effect immediately prior to the date of this Agreement, as required by applicable Law or as required to maintain the Tax qualified status of any Company Plan, (A) grant any Relevant Service Provider any increase in base salary or hourly wage rate, bonus opportunity or other material benefits (other than base salary (and corresponding annual bonus opportunity) increases made in the ordinary course of business consistent with past practice for employees whose annual base salary immediately prior to such increase does not exceed \$75,000), or pay any bonus of any kind to any Relevant Service Provider, (B) grant or pay to any Relevant Service Provider any severance, change in control or termination pay, or make any modifications thereto or increases therein, (C) grant or amend any award of stock options, stock appreciation rights, performance units, restricted stock, restricted stock units or other equity or equity-based awards, or remove or modify any restrictions in any Company Equity Plan or awards made thereunder, (D) adopt or enter into any collective bargaining agreement or other labor union Contract, (E) take any action to accelerate the vesting, funding or payment of any compensation or benefit under any Company Plan or otherwise, or (F) adopt, enter into or establish any new Company Plan or amend, modify or terminate any existing Company Plan;

(xvii) (A) hire any employee at the executive level or higher or (B) other than in the ordinary course of business consistent with past practice, hire any other employee;

(xviii) order or implement any plant closing, mass layoff or other similar action that requires the issuance of notice under the WARN Act or any similar state or local law;

(xix) enter into any collective bargaining agreement or other Contract with any union, works council or other labor organization;

(xx) terminate (or provide notice of termination to) any employee of the Company or any of its Subsidiaries with an annual base salary in excess of \$150,000 or otherwise request that any such employee of the Company or any of its Subsidiaries resign, in each case other than for cause or poor performance (consistent with the Company's past practices);

(xxi) fail to keep in force any material insurance policies or replace or revise provisions regarding insurance coverage in any material respect, in each case with respect to the assets, operations and activities of the Company and its Subsidiaries as currently in effect;

(xxii) renew or enter into any non-compete, exclusivity, non-solicitation or similar agreement that would restrict or limit, in any material respect, the operations of Parent or any of its Subsidiaries (including the Surviving Corporation or any of its Subsidiaries);

(xxiii) participate in any inspections, scheduled meetings or teleconferences with, or correspond in writing, communicate or consult with the FDA without providing Parent (whenever feasible and to the extent permitted under applicable Law) with prior written notice and, within twenty four (24) hours from the time such written notice is delivered, the opportunity to consult with the Company with respect to such inspection, correspondence, communication or consultation;

(xxiv) commence any new preclinical or clinical trial not initiated as of the date of this Agreement, or enter into any new line of business outside of its existing business;

(xxv) enter into any new real property lease or amend the terms of any existing real property lease; or

(xxvi) authorize any of, or commit or agree to take any of, the foregoing actions.

(b) Conduct of Business by Parent. During the period from the date of this Agreement to the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, except (i) as consented to in writing in advance by the Company, (ii) as otherwise specifically required by this Agreement, (iii) as set forth in Section 6.1(b) of the Parent Disclosure Letter, or (iv) as required by applicable Law, Parent shall, and shall cause each of its Subsidiaries to, carry on its business in the ordinary course consistent with past practice and use commercially reasonable efforts to preserve intact its business organization, preserve its material assets, rights and properties in good repair and condition and preserve its goodwill and maintain satisfactory relationships with customers, suppliers, licensors, licensees, distributors and others having business dealings with it and in compliance in all material respects with applicable Law and shall continue to pay outstanding accounts payable and other current liabilities (including payroll) when due in payable). In addition to and without limiting the generality of the foregoing, during the period from the date of this Agreement to the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, except (x) as specifically required by this Agreement, as required by applicable Law or (y) as set forth in Section 6.1(b) of the Parent Disclosure Letter, Parent shall not, and shall not permit any of its Subsidiaries, without the Company's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), to:

(i) (A) declare, set aside or pay any dividends on, or make any other distributions (whether in cash, equity interests or property) in respect of, any of the shares of capital stock or other equity interests, except for dividends by a wholly owned Subsidiary of Parent to its Parent, (B) purchase, redeem or otherwise acquire shares of capital stock or other equity interests of Parent or its Subsidiaries or any options, warrants, or rights to acquire any such shares of capital stock or other equity interests, except for the withholding of shares of Parent Common Stock in satisfaction of the applicable exercise price and/or withholding Taxes upon the settlement of Parent RSUs or exercise of Parent Options or Parent Warrants, or (C) split, combine, reclassify or otherwise amend the terms of any of its capital stock or other equity interests or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or other equity interests (other than the repurchase of shares of Parent Common Stock from terminated employees, directors or consultants or issuance of shares of Parent Common Stock issued upon the exercise of Parent Options, Parent Warrants or settlement of Parent RSUs, in each case under this clause (i), outstanding on the Measurement Date (to the extent issued in accordance with their terms as in effect on the Measurement Date));

(ii) issue, deliver, sell, grant, pledge or otherwise encumber or subject to any Lien (other than Permitted Liens) any shares of its capital stock or other equity interests or any securities convertible into, or exchangeable for or exercisable for any such shares or other equity interests, or any rights, warrants or options to acquire, any such shares or other equity interests, or any stock appreciation rights, “phantom” stock rights, performance units, rights to receive shares of capital stock of Parent on a deferred basis or other rights linked to the value of shares of Parent Common Stock, including pursuant to Contracts as in effect on the date hereof (other than the issuance of shares of Parent Common Stock issued upon the exercise of Parent Options or Parent Warrants or settlement of Parent RSUs, in each case outstanding on the Measurement Date (to the extent issued in accordance with their terms as in effect on the Measurement Date)), except for any issuance of Parent Common Stock in connection with any equity financing the proceeds of which will be used to increase Parent Net Cash in excess of \$12,000,000; provided, however, that Parent shall have informed the Company of a bona fide plan to take such action prior to the Company having exercised its rights under Section 8.1(h) herein;

(iii) except as required to give effect to anything in contemplation of Closing (including the Parent Reverse Split, if any), amend or otherwise change, or authorize the amendment or change of, its certificate of incorporation or by-laws (or similar organizational documents) (whether by merger, consolidation or otherwise);

(iv) form any Subsidiary or directly or indirectly acquire or agree to acquire (A) by merging or consolidating with, purchasing a substantial equity interest in or a substantial portion of the assets of, making an investment in or loan or capital contribution to or in any other manner, any corporation, partnership, association or other business organization or division thereof or (B) any assets that are otherwise material to Parent and its Subsidiaries, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the transactions contemplated by this Agreement;

(v) directly or indirectly sell, lease, license, sell and leaseback, abandon, mortgage or otherwise encumber or subject to any Lien (other than a Permitted Lien) or otherwise dispose in whole or in part of any of its material properties, assets or rights or any interest therein (including any Parent Owned IP), except (i) any Permitted Asset Disposition and (ii) the granting of non-exclusive licenses of Intellectual Property in the ordinary course of business consistent with past practice, the abandonment of Intellectual Property in the exercise of the good faith business judgment of Parent and the expiration of Intellectual Property in accordance with the applicable statutory term to the extent not extendable;

(vi) adopt or enter into a plan of complete or partial liquidation, dissolution, restructuring, recapitalization or other reorganization;

(vii) (A) incur, create, assume or otherwise become liable for, or repay or prepay, any Indebtedness for borrowed money, or amend, modify or refinance any Indebtedness of borrowed money, or (B) make any loans, advances or capital contributions to, or investments in, any other Person, other than Parent or any direct or indirect wholly owned Subsidiary of Parent;

(viii) incur or commit to incur any capital expenditure or authorization or commitment with respect thereto that in the aggregate are in excess of \$100,000;

(ix) (A) pay, discharge, settle or satisfy any claims, liabilities or obligations (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than the payment, discharge or satisfaction in the ordinary course of business consistent with past practice or as required by their terms as in effect on the date of this Agreement of claims, liabilities or obligations reflected or reserved against in the Parent SEC Documents or incurred since the date of such financial statements in the ordinary course of business consistent with past practice, (B) cancel any material Indebtedness owed to Parent or any of its Subsidiaries, or (C) waive, release, grant or transfer any right of material value, in each case other than any Permitted Asset Disposition;

(x) (A) materially modify, materially amend, terminate, cancel or extend any Parent Material Contract or (B) other than in the ordinary course of business consistent with past practice, enter into any Contract that if in effect on the date hereof would be a Parent Material Contract (other than any Contract for a Permitted Asset Disposition);

(xi) except with respect to an Action to enforce its rights under this Agreement, commence any Action (other than an Action as a result of an Action commenced against Parent or any of its Subsidiaries), or compromise, settle or agree to settle any Action (including any Action relating to this Agreement or the transactions contemplated by this Agreement) other than compromises, settlements or agreements in the ordinary course of business consistent with past practice that involve only the payment of money damages not in excess of \$50,000 individually or \$100,000 in the aggregate, in any case without the imposition of any equitable relief on, or the admission of wrongdoing by, Parent or any of its Subsidiaries; provided, however, that this clause (xi) shall not apply to any Action the defense of which is under the control of any insurer of Parent or any of its Subsidiaries;

(xii) change its financial or tax accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or applicable Law, or revalue any of its material assets;

(xiii) make any change in the policies of the Company or any of its Subsidiaries as in effect on the date of this Agreement with respect to cash management practices, including the payment of accounts payable or accrued expenses or the collection of accounts receivable or other receivables, or otherwise make any change with respect to the management of working capital;

(xiv) settle or compromise any material liability for Taxes; file any amended Tax Return or surrender any claim for a Tax refund; make, revoke or modify any entity classification or other material Tax election; file any Tax Return other than on a basis consistent with past practice; consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of Taxes; grant any power of attorney with respect to Taxes; or enter into any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, Tax holiday or any closing or other similar agreement (other than an agreement entered into in the ordinary course of business, the primary purpose of which is not related to Taxes), or change any method of accounting for Tax purposes;

(xv) change its fiscal year;

(xvi) except as required by the terms of any Parent Plan as in effect immediately prior to the date of this Agreement, as required by applicable Law or as required to maintain the tax qualified status of any Parent Plan, (A) grant any director, officer, employee or consultant any increase in base salary or hourly wage rate, bonus opportunity or other material benefits (other than base salary (and corresponding annual bonus opportunity) increases made in the ordinary course of business consistent with past practice for employees whose annual base salary immediately prior to such increase does not exceed \$75,000), or pay any bonus of any kind to any current or former director, officer, employee or consultant, (B) grant or pay to any current or former director, officer, employee or consultant any severance, change in control or termination pay, or make any modifications thereto or increases therein (other than as the automatic and non-discretionary result of a permitted base salary or annual bonus opportunity increase under the immediately preceding clause (A)), (C) grant or amend any award of stock options, stock appreciation rights, performance units, restricted stock, restricted stock units or other equity-based or equity-related awards, or remove or modify any restrictions in any Parent Equity Plan or awards made thereunder, (D) adopt or enter into any collective bargaining agreement or other labor union Contract, (E) take any action to accelerate the vesting, funding or payment of any compensation or benefit under any Parent Plan or (F) adopt, enter into or establish any new Parent Plan or materially amend, modify or terminate any existing Parent Plan;

(xvii) (A) hire any employee at the executive level or higher or (B) other than in the ordinary course of business consistent with past practice, hire any other employee;

(xviii) terminate (or provide notice of termination to) any executive officer of Parent with an annual base salary in excess of \$150,000 or otherwise request that any such executive officer resign, in each case other than for cause or poor performance (consistent with Parent's past practices);

(xix) fail to keep in force any material insurance policies or replace or revise provisions regarding insurance coverage in any material respect, in each case with respect to the assets, operations and activities of Parent and its Subsidiaries as currently in effect;

(xx) renew or enter into any non-compete, exclusivity, non-solicitation or similar agreement that would restrict or limit, in any material respect, the operations of Parent or any of its Subsidiaries (other than any exclusivity for a Permitted Asset Disposition);

(xxi) participate in any inspections, scheduled meetings or teleconferences with, or correspond in writing, communicate or consult with the FDA without providing the Company (whenever feasible and to the extent permitted under applicable Law) with prior written notice and, within twenty four (24) hours from the time such written notice is delivered, the opportunity to consult with Parent with respect to such inspection, correspondence, communication or consultation;

(xxii) commence any new preclinical or clinical trial not initiated as of the date of this Agreement, or enter into any new line of business outside of its existing business;

(xxiii) enter into any new real property lease or amend the terms of any existing real property lease;

(xxiv) after the Parent Net Cash is finalized pursuant to [Section 6.24](#), incur any cash expense other than in the ordinary course of business consistent with past practices or in connection with the transactions contemplated by this Agreement (including payment of Transaction Related Expenses); or

(xxv) authorize any of, or commit or agree to take any of, the foregoing actions.

Section 6.2 [No Company Solicitation](#).

(a) During the period between the date hereof and the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, the Company shall, and shall cause its Subsidiaries and the Company's and its Subsidiaries' respective directors and officers to, and shall instruct the Company's legal and financial advisors to: (i) following execution of this Agreement, immediately cease any existing solicitations, discussions or negotiations with any Third Persons that may be ongoing with respect to any inquiry, proposal, discussion, offer or request that constitutes or would reasonably be expected to lead to a Company Acquisition Proposal (a "[Company Inquiry](#)") and (ii) as promptly as reasonably practicable following the date hereof, request the prompt return or destruction (to the extent provided for by the applicable confidentiality agreement) of all confidential information previously furnished to any Third Person in connection with a Company Acquisition Proposal. The Company shall not, and shall cause its Subsidiaries and the Company's and its Subsidiaries' respective directors and officers not to, and shall not authorize any of its or its Subsidiaries' other Representatives to, during the period until the earlier of the Closing or the date, if any, on which this Agreement is terminated pursuant to [Section 8.1](#), (i) (A) directly or indirectly, solicit, initiate, knowingly encourage or knowingly facilitate any Company Inquiry, (B) furnish non-public information to or afford access to the business, employees, officers, contracts, properties, assets, books and records of the Company and the Company Subsidiaries to any Person in connection with a Company Inquiry or a Company Acquisition Proposal, or (C) enter into, continue or otherwise participate in any discussions or negotiations with any Third Person with respect to a Company Inquiry or a Company Acquisition Proposal (other than informing such Third Persons of the provisions set forth in this [Section 6.2\(a\)](#)), (ii) waive, terminate, modify or fail to enforce any provision of any "standstill" or similar obligation of any Third Person with respect to the Company or any of its Subsidiaries (unless the Company Board concludes in good faith, after consultation with its outside legal advisors, that the failure to so waive, terminate, modify or fail to enforce would be inconsistent with its fiduciary duties under applicable Law) or (iii) enter into any letter of intent or agreement in principle or any agreement with any Third Person by or on behalf of the Company or any of its Subsidiaries providing for any Company Acquisition Proposal.

(b) If the Company or any Representative of the Company receives a Company Acquisition Proposal or Company Inquiry at any time during the period until the earlier of the Closing or the date, if any, on which this Agreement is terminated pursuant to [Section 8.1](#), then the Company shall promptly inform (and in no event later than one (1) Business Day after the Company becomes aware of such Company Acquisition Proposal or Company Inquiry) Parent orally and in writing of such Company Acquisition Proposal or Company Inquiry (including the identity of the Person making or submitting such Company Acquisition Proposal or Company Inquiry, and the terms thereof). The Company shall keep Parent reasonably informed with respect to the status and terms of any such Company Acquisition Proposal or Company Inquiry and any material modification or proposed material modification thereto.

Section 6.3 [No Parent Solicitation](#).

(a) During the period between the date hereof and the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, Parent shall, and shall cause its Subsidiaries and Parent's and its Subsidiaries' respective directors and officers to, and shall instruct Parent's legal and financial advisors to: (i) following execution of this Agreement, immediately cease any existing solicitations, discussions or negotiations with any Third Persons that may be ongoing with respect to any inquiry, proposal, discussion, offer or request that constitutes or would reasonably be expected to lead to a Parent Acquisition Proposal (a "[Parent Inquiry](#)") and (ii) as promptly as reasonably practicable following the date hereof, request the prompt return or destruction (to the extent provided for by the applicable confidentiality agreement) of all confidential information previously furnished to any Third Person in connection with a Parent Acquisition Proposal. Parent shall not, and shall cause its Subsidiaries and the Parent's and its Subsidiaries' respective directors and officers not to, and shall not authorize any of its or its Subsidiaries' other Representatives to, during the period until the earlier of the Closing or the date, if any, on which this Agreement is terminated pursuant to [Section 8.1](#), (i) (A) directly or indirectly, solicit, initiate, knowingly encourage or knowingly facilitate any Parent Inquiry, (B) furnish non-public information to or afford access to the business, employees, officers, contracts, properties, assets, books and records of Parent and its Subsidiaries to any Third Person in connection with a Parent Inquiry or a Parent Acquisition Proposal, or (C) enter into, continue or otherwise participate in any discussions or negotiations with any Third Person with respect to a Parent Inquiry or a Parent Acquisition Proposal (other than informing such Third Person of the provisions set forth in this [Section 6.3\(a\)](#)), (ii) waive, terminate, modify or fail to enforce any provision of any "standstill" or similar obligation of any Third Person with respect to the Company or any of its Subsidiaries (unless the Parent Board concludes in good faith, after consultation with its outside legal advisors, that the failure to so waive, terminate, modify or fail to enforce would be inconsistent with its fiduciary duties under applicable Law) or (iii) enter into any letter of intent or agreement in principle or any agreement with any Third Person by or on behalf of Parent or any of its Subsidiaries providing for any Parent Acquisition Proposal.

(b) Notwithstanding the foregoing, if at any time following the date of this Agreement and prior to obtaining the Parent Stockholder Approval, (1) Parent receives a written Parent Acquisition Proposal that the Parent Board believes in good faith to be bona fide, (2) such Parent Acquisition Proposal was unsolicited and did not otherwise result from a breach of this [Section 6.3](#), (3) the Parent Board determines in good faith (after consultation with outside counsel and its financial advisor) that such Parent Acquisition Proposal constitutes or could be reasonably likely to result in a Superior Proposal, and (4) the Parent Board determines in good faith (after consultation with outside counsel) that the failure to take the actions referred to in clause (x) or (y) below would be inconsistent with its fiduciary duties to the stockholders of Parent under applicable Law, then Parent and its Representatives may (x) furnish information with respect to Parent and its Subsidiaries to the Third Person making such Parent Acquisition Proposal pursuant to an Acceptable Confidentiality Agreement; and (y) participate in discussions or negotiations with the Third Person making such Parent Acquisition Proposal regarding such Parent Acquisition Proposal, provided, that at least two (2) Business Days prior to furnishing any such non-public information to, or entering into discussions with, such Person, Parent gives the Company written notice of the identity of such Person and of Parent's intention to furnish nonpublic information to, or enter into discussions with, such Person and furnishes such non-public information to the Company (to the extent such information has not been previously furnished by Parent to the Company).

(c) Neither the Parent Board nor any committee thereof shall:

(i) make any Parent Adverse Recommendation Change; or

(ii) cause or permit Parent or any of its Subsidiaries to enter into any Alternative Acquisition Agreement, in each case constituting or related to, or which is intended to or is reasonably likely to lead to, any Parent Acquisition Proposal, or agree in writing or publicly propose to take any such actions.

Notwithstanding the foregoing, at any time prior to obtaining Parent Stockholder Approval, (I) the Parent Board may, if the Parent has received a *bona fide* written Acquisition Proposal (which Acquisition Proposal did not result from a breach of this [Section 6.3](#)) from any Person that has not been withdrawn and after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Proposal, and the Parent Board determines in good faith (after consultation with outside legal counsel) that the failure to do so would be inconsistent with its fiduciary duties to the stockholders of Parent under applicable Law, taking into account all adjustments to the terms of this Agreement that may be proposed by the Company pursuant to this [Section 6.3\(c\)](#), make a Parent Adverse Recommendation Change in response to a Superior Proposal or terminate this Agreement in accordance with [Section 8.1\(g\)](#) to enter into an Alternative Acquisition Agreement for such Superior Proposal; provided, however, that the Parent Board may not make a Parent Adverse Recommendation Change in response to a Superior Proposal or so terminate this Agreement to enter into an Alternative Acquisition Agreement for such Superior Proposal, unless:

(A) Parent notifies the Company in writing at least four (4) Business Days before taking that action of its intention to do so (the “Parent Notice Period”) (which notice shall not constitute a Parent Board Adverse Recommendation Change), and specifies the reasons therefor, including the terms and conditions of, and the identity of the Person making, such Superior Proposal, and contemporaneously furnishes a copy (if any) of the proposed Alternative Acquisition Agreement and any other relevant transaction documents (it being understood and agreed that if there is any material amendment to the terms of such Superior Proposal after the commencement of the Parent Notice Period (including any revision in price or percentage of the combined company that Parent’s stockholders would receive as a result of such Superior Proposal), the Parent Notice Period shall be extended to ensure that at least two (2) Business Days remain in the Parent Notice Period subsequent to the date Parent notifies the Company of the material amendment) (it being understood that there may be multiple extensions); and

(B) if the Company makes a proposal during such Parent Notice Period to adjust the terms and conditions of this Agreement, the Parent Board, after taking into consideration the adjusted terms and conditions of this Agreement as proposed by the Company (if any), continues to determine in good faith (after consultation with outside counsel and its financial advisor) that such Superior Proposal continues to be a Superior Proposal and that the failure to make a Parent Adverse Recommendation Change for such Superior Proposal would be inconsistent with its fiduciary duties to the stockholders of the Company under applicable Law;

and (II) the Parent Board may make a Parent Adverse Recommendation Change in response to a Parent Intervening Event, if:

(1) the Parent Board determines in good faith, after consultation with Parent’s outside legal counsel, that the failure to do so would be reasonably likely to be inconsistent with the fiduciary duties of the Parent Board to Parent’s stockholders under applicable Law;

(2) Parent notifies the Company in writing at least four (4) Business Days before making a Parent Adverse Recommendation Change with respect to such Parent Intervening Event of its intention to do so and specifies the reasons therefor; and

(3) if the Company makes a proposal during such five (4) Business Day period to adjust the terms and conditions of this Agreement, the Parent Board, after taking into consideration the adjusted terms and conditions of this Agreement as proposed by the Company (if any), continues to determine in good faith (after consultation with outside counsel) that the failure to make such Parent Adverse Recommendation Change would be inconsistent with its fiduciary duties to the stockholders of Parent under applicable Law.

During the Parent Notice Period (in the event of a Superior Proposal) or four (4) Business Day period (in the event of a Parent Intervening Event) prior to its effecting a Parent Adverse Recommendation Change, Parent shall, and shall cause its financial and legal advisors to, negotiate with the Company in good faith (to the extent the Company seeks to negotiate) regarding any revisions to the terms of the transactions contemplated by this Agreement proposed by the Company so that the applicable Parent Acquisition Proposal ceases to constitute a Superior Proposal or the failure to make a Parent Adverse Recommendation Change with respect to such Parent Intervening Event would not be inconsistent with the Parent Board’s fiduciary duties to the stockholders of Parent under applicable Law.

(d) In addition to the obligations of Parent set forth in [Section 6.3\(a\)](#), Parent promptly shall advise the Company in writing (and in any event within one (1) Business Day of Parent obtaining Knowledge) of the receipt by Parent, its Subsidiaries or any of their respective Representatives of any inquiry, proposal or offer that is reasonably likely to lead to or that contemplates a Parent Acquisition Proposal, in each case together with a description of the material terms and conditions of any such inquiry, proposal or offer, the identity of the Person making any such inquiry, proposal or offer, and a copy of any written proposal, offer or draft agreement provided by such Person. Parent shall thereafter keep the Company informed (orally and in writing) in all material respects on a prompt basis of the status and details of such inquiry, proposal or offer, including furnishing copies to the Company of any draft documentation, written summaries of any material oral inquiries or discussions and any amendments to the material terms and conditions thereof.

(e) Nothing contained in this Agreement shall prohibit Parent or the Parent Board from (i) taking and disclosing a position contemplated by Rules 14d-9 or 14e-2(a), promulgated under the Exchange Act regarding a Parent Acquisition Proposal, (ii) issuing a “stop, look and listen” communication or similar communication of the type contemplated by Section 14d-9(f) under the Exchange Act pending disclosure of its position thereunder or (iii) otherwise making any disclosure to Parent’s stockholders provided however, that any disclosure made by Parent or the Parent Board pursuant to the foregoing shall be limited to a statement that Parent is unable to take a position with respect to the bidder’s tender offer unless the Parent Board determines in good faith, after consultation with its outside legal counsel, that failure to make additional disclosure would be inconsistent with fiduciary duties under applicable Law; provided further however, that [Section 6.3\(e\)\(iii\)](#) shall not be deemed to permit the Parent or the Parent Board to make a Parent Adverse Recommendation Change or take any of the actions referred to in [Section 6.3\(c\)](#) except to the extent permitted by [Section 6.3\(c\)](#) (it being understood that any “stop, look and listen” communication or similar communication that contains only the information set forth in Rule 14d-9(f) shall not be deemed, in and of itself, a Parent Adverse Recommendation Change).

Section 6.4 [Preparation of the Proxy Statement; Parent Stockholders’ Meeting.](#)

(a) As promptly as practicable after the date of this Agreement, and in no event more than 45 days following the date of this Agreement (or such later date that is five (5) Business Days after the Company Audited Financial Statements and, if then required to be included in the Registration Statement, the Company Interim Financial Statements, in each case meeting the requirements of [Section 6.22\(a\)](#) (including with respect to the audited financial statements, the audit opinion thereon and the consent of the auditor to include such financial statements in the Registration Statement) have been made available to Parent), Parent and the Company shall jointly prepare and Parent shall cause to be filed with the SEC, in preliminary form, the Registration Statement, in which the Proxy Statement relating to the special meeting of Parent’s stockholders (the “[Parent Stockholders’ Meeting](#)”) will be included, in connection with the Parent Stockholder Matters and any other proposals mutually agreed by Parent and the Company.

(b) Parent shall use its commercially reasonable efforts to (A) have the Registration Statement declared effective under the Securities Act as promptly as practicable after such filing, (B) to keep the Registration Statement effective as long as is necessary to consummate the Parent Stockholder Matters and the other transactions contemplated hereby and (C) to ensure that the Registration Statement complies in all material respects with the applicable provisions of the Securities Act and Exchange Act. Parent shall use commercially reasonable efforts to cause the Proxy Statement to be mailed to Parent's stockholders as promptly as practicable after the Registration Statement is declared effective under the Securities Act. Prior to the Effective Time, Parent shall also take any action (other than qualifying to do business in any jurisdiction in which it is not now so qualified or filing a general consent to service of process) required to be taken under any applicable state securities or "blue sky" Laws in connection with the Parent Stock Issuance and Parent and the Company shall furnish all information concerning themselves and their respective equityholders as may be reasonably requested in connection with any such action. Except with respect to a Parent Adverse Recommendation Change specifically permitted by [Section 6.3](#), no filing of, or amendment or supplement to, the Registration Statement or the Proxy Statement will be made by Parent without providing the Company and its counsel a reasonable opportunity to review and comment thereon. If at any time prior to the Effective Time any information relating to Parent or the Company, or any of their respective Affiliates, officers or directors, should be discovered by Parent or the Company that should be set forth in an amendment or supplement to the Registration Statement or the Proxy Statement, so that any of such documents would not contain any misstatement of a material fact or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Party that discovers such information shall promptly notify the other Party and an appropriate amendment or supplement describing such information shall promptly be filed with the SEC and, to the extent required under applicable Law, disseminated to stockholders of Parent; provided, that the delivery of such notice and the filing of any such amendment or supplement shall not affect or be deemed to modify any representation or warranty made by any Party hereunder or otherwise affect the remedies available hereunder to any Party hereunder.

(c) To the extent not prohibited by Law, Parent will advise the Company, reasonably promptly after Parent receives notice thereof, of the time when the Registration Statement or any supplement or amendment has been filed, or of any request by the SEC for the amendment or supplement of the Registration Statement or for additional information. To the extent not prohibited by Law, the Company and its counsel shall be given a reasonable opportunity to review and comment on the Registration Statement and any other document filed or furnished to the SEC each time before any such document is filed or furnished with the SEC, and Parent shall give reasonable and good faith consideration to any comments made by the Company and its counsel. To the extent not prohibited by Law, Parent shall provide the Company and its counsel with (A) any comments or other communications, whether written or oral, that Parent or its counsel may receive from time to time from the SEC or its staff with respect to the Registration Statement promptly after receipt of those comments or other communications and (B) a reasonable opportunity to participate in the response of Parent to those comments and to provide comments on that response (to which reasonable and good faith consideration shall be given), including by participating with the Company or its counsel in any discussions or meetings with the SEC (to the extent permitted by the SEC).

(d) The Company shall reasonably cooperate with Parent and provide, and require its Representatives to provide, Parent and its Representatives, with all true, correct and complete information regarding the Company or its Subsidiaries that is required by Law to be included in the Registration Statement or reasonably requested by Parent to be included in the Registration Statement, including as contemplated by [Section 6.15](#). Without limiting the foregoing, the Company will use commercially reasonable efforts to cause to be delivered to Parent a consent letter of such Party's independent accounting firm, dated no more than two (2) Business Days before the date on which the Registration Statement becomes effective (and reasonably satisfactory in form and substance to Parent), that is customary in scope and substance for consent letters delivered by independent public accountants in connection with registration statements similar to the Registration Statement.

(e) Promptly after the Registration Statement is declared effective under the Securities Act, Parent shall take all action necessary under applicable Law to call, give notice of and hold the Parent Stockholders' Meeting. Parent shall use commercially reasonable efforts to hold the Parent Stockholders' Meeting as promptly as practicable after the Proxy Statement is declared effective under the Securities Act and, in any event, no later than forty-five (45) calendar days after the effective date of the Registration Statement; provided, however, in the event that Parent stockholder approval for the Parent Reverse Split is sought by Parent, Parent shall hold the Parent Stockholders' Meeting no later than sixty (60) calendar days after the effective date of the Registration Statement. Parent shall take reasonable measures to ensure that all proxies solicited by it in connection with the Parent Stockholders' Meeting are solicited in compliance with all applicable Law. Notwithstanding anything to the contrary contained herein, if on the date of the Parent Stockholders' Meeting, or a date preceding the date on which the Parent Stockholders' Meeting is scheduled, Parent reasonably believes that (i) it will not receive proxies sufficient to obtain the Parent Stockholder Approval, whether or not a quorum would be present, or (ii) it will not have sufficient shares of Parent Common Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Parent Stockholders' Meeting, Parent may recess, postpone or adjourn, or make one or more successive postponements or adjournments of, the Parent Stockholders' Meeting as long as the date of the Parent Stockholders' Meeting is not postponed or adjourned more than an aggregate of sixty (60) days in connection with any postponements or adjournments, except as may be required to allow reasonable additional time for the filing and mailing of any supplemental or amended disclosure which the SEC or its staff has instructed Parent is necessary under applicable Law and for such supplemental or amended disclosure to be disseminated and reviewed by the Parent stockholders prior to the Parent Stockholders' Meeting or as required by applicable Law.

(f) Subject to [Section 6.3](#), Parent agrees that the Proxy Statement shall include the Parent Board Recommendation and shall use commercially reasonable efforts to solicit such approval within the timeframe set forth in [Section 6.4\(e\)](#).

(g) Without prejudice to Parent's right to terminate this Agreement in accordance with [Article VIII](#) or Parent's rights under [Section 6.3](#), Parent's obligation to call, give notice of and hold the Parent Stockholders' Meeting in accordance with this [Section 6.4](#) shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Superior Proposal or Acquisition Proposal, or by any Parent Adverse Recommendation Change.

(h) Notwithstanding the foregoing in this [Section 6.4](#), following the date of this Agreement and prior to the filing of the Registration Statement with the SEC pursuant to [Section 6.4\(a\)](#), the Parties shall reasonably cooperate (and consult with Nasdaq, if the Parties deem appropriate), as applicable, regarding alternatives to the filing of the Registration Statement that the Parties mutually agree would reasonably be expected to expedite the consummation of the transactions contemplated by this Agreement, including conducting the Parent Stock Issuance by means of a private placement pursuant to Section 4(2) of the Securities Act and requiring the filing by Parent of a resale registration statement for the former holders of Company Common Stock receiving shares of Parent Common Stock in the Merger.

Section 6.5 [Company Stockholder Approval](#).

(a) No later than one (1) Business Day after the effective date of the Registration Statement, the Company shall obtain and deliver evidence to Parent of the execution and delivery of the Company Stockholder Written Consent from holders of Company Capital Stock (all of which holders shall have delivered properly completed and duly executed Company Stockholder Letter indicating that they are Accredited Holders), sufficient for the Company Stockholder Approval under the DGCL and the Company's Organizational Documents, in lieu of a meeting pursuant to Section 228 of the DGCL and the Company's Organizational Documents in a form reasonably acceptable to Parent, for purposes of (i) adopting and approving this Agreement and the transactions contemplated by this Agreement, (ii) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares pursuant to Section 262 of the DGCL, a true and correct copy of which will be attached thereto, and that such stockholder has received and read a copy of Section 262 of the DGCL, and (iii) acknowledging that by its approval of the Merger it is not entitled to appraisal rights with respect to its shares of Company Capital Stock in connection with the Merger and thereby waives any rights to receive payment of the fair value of its shares of capital stock under the DGCL. Under no circumstances shall the Company assert that any other approval or consent is necessary by its stockholders to approve this Agreement and the transactions contemplated by this Agreement.

(b) Reasonably promptly following receipt of the Company Stockholder Approval, the Company shall prepare and mail a notice (the "[Stockholder Notice](#)") to every stockholder of the Company that did not execute the Company Stockholder Written Consent. The Stockholder Notice shall (i) be a statement to the effect that the Company Board determined that the Merger is advisable in accordance with Section 251 of the DGCL and in the best interests of the stockholders of the Company and approved and adopted this Agreement, the Merger and the other transactions contemplated by this Agreement, (ii) provide the stockholders of the Company to whom it is sent with notice of the actions taken in the Company Stockholder Written Consent, including the adoption and approval of this Agreement, the Merger and the other transactions contemplated by this Agreement in accordance with Section 228 of the DGCL and the Organizational Documents of the Company and (iii) include a description of the appraisal rights of the Company's stockholders available under the DGCL, along with such other information as is required thereunder and pursuant to applicable Law. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this [Section 6.5](#) shall be subject to Parent's advance review and reasonable approval. The Parties shall reasonably cooperate with each other and provide, and cause their respective Representatives to provide, the other Party and its Representatives with all true, correct and complete information regarding such Party or its Subsidiaries that is required to be included in the Stockholder Notice or reasonably requested to be included in the Stockholder Notice.

(c) The Company agrees that: (i) the Company Board shall recommend to the Company's stockholders the Company Board Recommendation; and (ii) the Company Board Recommendation shall not be withdrawn or modified (and the Company Board shall not publicly propose to withdraw or modify the Company Board Recommendation) in a manner adverse to Parent, and no resolution by the Company Board or any committee thereof to withdraw or modify the Company Board Recommendation in a manner adverse to Parent or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any Company Acquisition Proposal shall be adopted or proposed. The Company shall use its commercially reasonable efforts to cause to be exercised promptly following the execution and delivery of this Agreement any rights it or its Affiliates have to require any holder of Company Capital Stock to deliver such holder's written consent pursuant to the Company Stockholder Written Consent.

(d) The Company's obligation to solicit the consent of its stockholders to sign the Company Stockholder Written Consent in accordance with [Section 6.5\(a\)](#) shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Company Acquisition Proposal.

Section 6.6 Access to Information; Confidentiality.

(a) The Company shall, and shall cause each of its Subsidiaries to, afford to Parent and its Representatives reasonable access during normal business hours and upon reasonable advance notice, during the period prior to earlier of the Effective Time or the termination of this Agreement in accordance with its terms, (i) to such information concerning the business, properties, assets and personnel of the Company and its Subsidiaries as Parent or its Representatives may reasonably request (including the books and records of the Company and its Subsidiaries and Tax Returns filed and those in preparation and the work papers of its auditors) and (ii) reasonable access to all properties and personnel (in a manner so as to not unreasonably interfere with the normal business operations of the Company and its Subsidiaries).

(b) Parent shall, and shall cause each of its Subsidiaries to, afford to the Company and its Representatives reasonable access during normal business hours and upon reasonable advance notice, during the period prior to the earlier of the Effective Time or the termination of this Agreement in accordance with its terms, to (i) such information concerning the business, properties, assets and personnel of Parent and its Subsidiaries as the Company or its Representatives may reasonably request (including the books and records of Parent and its Subsidiaries and Tax Returns filed and those in preparation and the work papers of its auditors) and (ii) reasonable access to all properties and personnel (in a manner so as to not unreasonably interfere with the normal business operations of Parent and its Subsidiaries).

(c) This [Section 6.6](#) shall not require a party hereunder to permit any access, or to disclose any information, that in its reasonable, good faith judgment (after consultation with outside counsel) would reasonably be expected to result in (i) any violation of any Law to which such party is subject or cause any privilege (including attorney-client privilege) which the such party or any of its Subsidiaries would be entitled to assert to be undermined with respect to such information, provided that the parties shall use their commercially reasonable efforts to find a way to permit disclosure of such information, or (ii) if the Company and its Subsidiaries, on the one hand, and Parent or any of its Subsidiaries, on the other hand, are adverse parties in an Action, such information being reasonably pertinent thereto

(d) All information shared pursuant to this [Section 6.6](#) shall be held confidential in accordance with the terms of the Confidentiality Agreement between Parent and the Company dated October 18, 2022 (the “[Confidential Disclosure Agreement](#)”). No investigation pursuant to this [Section 6.6](#) or information provided, made available or delivered to any party pursuant to this Agreement shall affect any of the representations, warranties, covenants, rights or remedies, or the conditions to the obligations of, the parties hereunder.

Section 6.7 [Commercially Reasonable Efforts.](#)

(a) Upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use commercially reasonable efforts to take, or cause to be taken, all actions that are necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the Merger and the other transactions contemplated by this Agreement, including using commercially reasonable efforts to accomplish the following: (i) obtain all required consents, approvals or waivers from, or participation in other discussions or negotiations with, Third Persons, (ii) obtain all necessary Actions or non-Actions, waivers, consents, approvals, Orders and authorizations from Governmental Entities, make all necessary registrations, declarations and filings and make all commercially reasonable efforts to obtain an approval or waiver from, or to avoid any Action by, any Governmental Entity, (iii) vigorously resist and contest any Action, including administrative or judicial Action, and seek to have vacated, lifted, reversed or overturned any Order (whether temporary, preliminary or permanent) that is in effect and that could restrict, prevent or prohibit consummation of the Merger and the other transactions contemplated by this Agreement, including, without limitation, by vigorously pursuing all avenues of administrative and judicial appeal and (iv) execute and deliver any additional instruments necessary to consummate the transactions contemplated by this Agreement and fully to carry out the purposes of this Agreement; provided, however, that none of the Company, Parent or any of its respective Subsidiaries shall commit to the payment of any fee, penalty or other consideration or make any other concession, waiver or amendment under any Contract in connection with obtaining any consent without the prior written consent of the Company (with respect to the Company and its Subsidiaries) or Parent (with respect to Parent and its Subsidiaries). Each of the Parties shall furnish to each other party such necessary information and reasonable assistance as such other party may reasonably request in connection with the foregoing. Subject to applicable Law relating to the exchange of information, Parent and the Company shall each have the right to review in advance, and to the extent practicable each shall consult with the other in connection with, all of the information relating to Parent or the Company, as the case may be, and any of their respective Subsidiaries, that appears in any filing made with, or written materials submitted to, any Third Person and/or any Governmental Entity in connection with the Merger and the other transactions contemplated by this Agreement. In exercising the foregoing rights, each of Parent and the Company shall act reasonably and as promptly as practicable. Subject to applicable Law and the instructions of any Governmental Entity, the Company and Parent, to the extent practicable under the circumstances, shall provide the other party and its counsel with the opportunity to participate in any meeting with any Governmental Entity in respect of any filing, investigation or other inquiry in connection with the transactions contemplated by this Agreement.

(b) Notwithstanding any other provision of this Agreement to the contrary, in no event shall any Party or any of its Affiliates be required to (i) agree or proffer to divest or hold separate (in a trust or otherwise), or take any other action with respect to, any of the assets or businesses of such Party or any of its Affiliates or, assuming the consummation of the Merger, the Surviving Corporation or any of its Affiliates, (ii) agree or proffer to limit in any manner whatsoever or not to exercise any rights of ownership of any securities (including the shares of Company Common Stock) or (iii) enter into any agreement that in any way limits the ownership or operation of any business of Parent, the Company, the Surviving Corporation or any of their respective Affiliates.

Section 6.8 Takeover Laws. Each of Parent, the Parent Board, the Company and the Company Board shall (a) take no action to cause any Takeover Law to become applicable to this Agreement, the Merger or any of the other transactions contemplated by this Agreement and (b) if any Takeover Law is or becomes applicable to this Agreement, the Merger or any of the other transactions contemplated by this Agreement, take all action necessary to ensure that the Merger and the other transactions contemplated by this Agreement may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise to minimize the effect of such Takeover Law with respect to this Agreement, the Merger and the other transactions contemplated by this Agreement.

Section 6.9 Notification of Certain Matters. Parent and the Company shall promptly, but in no event later than one (1) Business Day after becoming aware, notify each other of (a) any notice or other communication received by such Party from (x) any Governmental Entity in connection with the Merger or the other transactions contemplated by this Agreement or (y) from any Person alleging that the consent of such Person is, or may be, required in connection with the transactions contemplated by this Agreement, (b) any Action commenced or, to such Party's Knowledge, threatened against, relating to or involving or otherwise affecting such party or any of its Subsidiaries which relate to the transactions contemplated by this Agreement or (c) any change, condition or event between the date of this Agreement and the Effective Time which causes or is reasonably likely to cause the failure of the conditions set forth in Section 7.2(a), Section 7.2(b), or Section 7.2(d) of this Agreement (in the case of the Company) or Section 7.3(a), Section 7.3(b), or Section 7.3(d) of this Agreement (in the case of Parent), to be satisfied; provided, however, that no such notification shall affect any of the representations, warranties, covenants, rights or remedies, or the conditions to the obligations of, the parties hereunder. This Section 6.9 shall not constitute an obligation for purposes of Section 7.2(b) or Section 7.3(b).

Section 6.10 Indemnification, Exculpation and Insurance.

(a) From the Effective Time through the sixth (6th) anniversary of the date on which the Effective Time occurs (the “Indemnification Period”), Parent and the Surviving Corporation shall, jointly and severally, indemnify and hold harmless each individual who is now, or has been at any time prior to the date of this Agreement, or who becomes prior to the Effective Time, a director or officer (or equivalent) of Parent, the Company or any of their respective Subsidiaries (each, an “Indemnified Party”), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys’ fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, (i) by reason of the fact that the Indemnified Party is or was a director or officer of Parent, the Company or any of their respective Subsidiaries or (ii) arising out of or pertaining to matters existing or occurring at or prior to the Effective Time (including this Agreement and the transactions and actions contemplated by this Agreement) (in each case, a “D&O Related Claim”), whether asserted or claimed prior to, at or after the Effective Time, in each case, to the fullest extent permitted under applicable Law. Each Indemnified Party will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from Parent or the Surviving Corporation, within ten (10) Business Days of receipt by Parent or the Surviving Corporation from the Indemnified Party of a request therefor; provided that any such person to whom expenses are advanced provides an undertaking to Parent, to the extent then required by applicable Law, to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

(b) The provisions of the Organizational Documents of Parent and its Subsidiaries (including the Surviving Corporation) with respect to indemnification, advancement of expenses and exculpation of the Indemnified Parties that are presently set forth in their Organizational Documents shall not be amended, modified or repealed during the Indemnification Period in a manner that would adversely affect the rights thereunder of the Indemnified Parties, unless such modification is required by applicable Law. During the Indemnification Period, Parent and the Surviving Corporation shall cause the Organizational Documents of Parent and the Surviving Corporation to contain, and Parent shall cause the Organizational Documents of its Subsidiaries (including the Surviving Corporation) to so contain, provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of the Indemnified Parties as those set forth in the Organizational Documents of Parent and its Subsidiaries (including the Surviving Corporation), respectively, as of the date of this Agreement.

(c) From and after the Effective Time, Parent and the Surviving Corporation, shall, jointly and severally, fulfill and honor (or cause to be fulfilled or honored) in all respects the obligations of Parent its Subsidiaries (including the Surviving Corporation) to the applicable Indemnified Parties pursuant to any indemnification agreements between Parent, the Company or any of their respective Subsidiaries, on the one hand, and such Indemnified Parties, on the other hand, in each case as in effect as of the date of this Agreement, with respect to claims arising out of matters occurring at or prior to the Effective Time.

(d) During the Indemnification Period, Parent shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Parent. In addition, (i) to the extent required as a result of the termination of coverage under Parent's directors' and officers' liability insurance policy in effect prior to the Closing (including any renewal and/or continuation thereof), Parent shall purchase, prior to the Effective Time, a six (6)-year prepaid "tail policy" (the cost of which shall be a Parent Transaction Related Expense) for the non-cancellable extension of the directors' and officers' liability coverage of Parent's existing directors' and officers' insurance policies for a claims reporting or discovery period of at least six (6) years from and after the date on which the Effective Time occurs with respect to any claim related to any period of time at or prior to the Effective Time, with the scope of errors and omissions covered by such insurance reasonably comparable to that provided under Parent's existing policies as of the date of this Agreement with respect to actual or alleged errors, misleading statements, acts, omissions, neglect, breaches of duty or matters claimed against a director or officer of Parent by reason of him or her serving in such capacity that existed or occurred prior to the Effective Time (including in connection with this Agreement or the transactions contemplated hereby) (the "Parent D&O Tail Policy"). Additionally, at the Company's request and at the Company's sole expense (the expense for which shall be added to Parent Net Cash), Parent shall add the Company and its Subsidiaries as additional insureds solely in their capacity as Parent's successors in interest on the Parent D&O Tail Policy on Parent's behalf.

(e) From and after the Effective Time, Parent and the Surviving Corporation shall, jointly and severally, pay all expenses, including reasonable attorneys' fees, that are incurred by the Indemnified Parties in connection with their successful enforcement of the rights provided to such individuals in this Section 6.10.

(f) The provisions of this Section 6.10 are intended to be in addition to the rights otherwise available to the Indemnified Parties by Law, charter, statute, bylaw or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the Indemnified Parties, their heirs and their representatives.

(g) In the event Parent or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall succeed to the obligations set forth in this Section 6.10. Parent shall cause such Surviving Corporation to perform all of the obligations of the Surviving Corporation under this Section 6.10.

(h) Notwithstanding any time limit herein to the contrary, if claim is made hereunder on or prior to the sixth (6th) anniversary of the date on which the Effective Time occurs, the provisions of this Section 6.10 (without regard to any such time limit) shall continue in effect with respect to such claim until the final disposition of such D&O Related Claim.

(i) This [Section 6.10](#) shall survive the consummation of the Merger at the Effective Time, is intended to benefit Parent, the Company, the Surviving Corporation and the Indemnified Parties, shall be binding on all successors and assigns of Parent and the Surviving Corporation and shall be enforceable by the Indemnified Parties and their respective heirs, legatees, representatives, successors and assigns, in each case as if such Persons were party hereto. The obligations of Parent and the Surviving Corporation under this [Section 6.10](#) shall not be terminated or modified in such a manner as to adversely affect any Indemnified Party to whom this [Section 6.10](#) applies without the consent of the affected Indemnified Party, it being expressly agreed that the Indemnified Parties to whom this [Section 6.10](#) applies shall be third party beneficiaries of this [Section 6.10](#).

Section 6.11 [Stock Exchange Listing](#).

(a) Parent shall use its commercially reasonable efforts, (i) to maintain its existing listing on Nasdaq until the Closing Date and to obtain approval of the listing of the combined company on Nasdaq, (ii) prepare and submit a notification form for the listing of the shares of Parent Common Stock to be issued in the Merger and cause such shares to be approved for listing (subject to official notice of issuance), (iii) to effect the Parent Reverse Split (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application), and (iv) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial listing application for the Parent Common Stock on Nasdaq (the "[Nasdaq Listing Application](#)") and to cause such Nasdaq Listing Application to be conditionally approved prior to the Effective Time. Parent shall pay all Nasdaq fees associated with the Nasdaq Listing Application (the cost of which shall be shared equally by Parent and the Company as a Parent Transaction Related Expense and a Company Transaction Related Expense, respectively).

(b) Each of the Parties will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations. Each of the Parties will cooperate with the other as reasonably requested by the other with respect to the Nasdaq Listing Application and promptly furnish all information concerning itself and its stockholders or members, as the case may be, that may be required or reasonably requested in connection with any action contemplated by this [Section 6.11](#).

Section 6.12 [Public Announcements](#). Prior to the Effective Time, each of Parent and the Company shall, to the extent reasonably practicable, consult with each other before issuing, and give each other a reasonable opportunity to review and comment upon, any press release or other public statements with respect to this Agreement, the Merger and the other transactions contemplated by this Agreement and shall not issue any such press release or make any public announcement prior to such consultation and review, except as may be required by applicable Law, court process or by obligations pursuant to any listing agreement with any national securities exchange or national securities quotation system. The initial press release of the parties announcing the execution of this Agreement shall be a joint press release of Parent and the Company in a form that is mutually agreed. Notwithstanding the foregoing, the restrictions set forth in this [Section 6.12](#) shall not apply to any release, announcement or statement made or proposed to be made in connection with and related to a Parent Adverse Recommendation Change, or any disclosures made in compliance with [Section 6.3](#). Notwithstanding the foregoing, each of the Company and Parent may make any public statements in response to specific questions by the press, analysts, investors or those attending industry conferences or analyst or investor conference calls, so long as such statements are consistent with previous press releases, public disclosures or public statements made by the Company or Parent in compliance with this [Section 6.12](#).

Section 6.13 Employee Matters.

(a) For a period of twelve (12) months following the Closing Date, but not beyond the date on which a Parent Continuing Employee's (as defined below) employment with the Company or any of its Subsidiaries terminates (the "Continuation Period"), Parent shall, or shall cause one of its Subsidiaries (including, after the Effective Time, the Surviving Corporation and their respective Subsidiaries) to, provide to each individual employed by Parent or any of its Subsidiaries immediately prior to the Effective Time (each, a "Parent Continuing Employee") (i) the base salary or hourly wages and incentive compensation opportunity amounts that are no less favorable in the aggregate to those provided to the Parent Continuing Employee immediately prior to the Effective Time and (ii) all other employee benefits (excluding retiree medical, dental, vision, prescription drug, life insurance and defined benefit pension plan benefits) that are substantially comparable in the aggregate to the such employee benefits provided to the Parent Continuing Employee immediately prior to the Effective Time. Nothing herein shall prevent Parent or any of its Subsidiaries (including, after the Effective Time, the Surviving Corporation or any of its Subsidiaries) from terminating the employment of any Parent Continuing Employee at any time and for any reason, including during the Continuation Period.

(b) For purposes of vesting, eligibility to participate, and level of benefits under the benefit plans, programs, contracts or arrangements of Parent or any of its Subsidiaries (including, following the Closing, the Surviving Corporation and its Subsidiaries) providing benefits to any Continuing Employee after the Effective Time (the "Post-Effective Plans"), each employee who continues to be employed by Parent, the Company or any of their respective Subsidiaries immediately following the Effective Time ("Continuing Employees") shall be credited with his or her years of service with Parent, the Company or any of their respective Subsidiaries and their respective predecessors; provided that the foregoing shall not apply to the extent that its application would result in a duplication of benefits. In addition, and without limiting the generality of the foregoing, for purposes of each Post-Effective Plan providing medical, dental, pharmaceutical and/or vision benefits to a Continuing Employee, Parent shall cause all pre-existing condition exclusions and actively-at-work requirements of such Post-Effective Plan to be waived for such Continuing Employee and his or her covered dependents to the extent such conditions would have been waived or satisfied under the employee benefit plan whose coverage is being replaced under the Post-Effective Plan, and Parent shall use commercially reasonable efforts to cause any eligible expenses incurred by a Continuing Employee and his or her covered dependents during the portion of such plan year in which coverage is replaced with coverage under such a Post-Effective Plan to be taken into account under such Post-Effective Plan with respect to the plan year in which participation in such Post-Effective Plan begins for purposes of satisfying all deductible, coinsurance and maximum out-of-pocket requirements applicable to such Continuing Employee and his or her covered dependents for such plan year as if such amounts had been paid in accordance with such Post-Effective Plan.

(c) Parent and the Company acknowledge and agree that all provisions contained in this [Section 6.13](#) are included for the sole benefit of the respective parties to this Agreement and shall not create any right in any other Person, including any right to continued employment or service with Parent, the Company or any of their respective Subsidiaries. Without limiting the generality of the foregoing, nothing in this [Section 6.13](#) shall be deemed to (i) establish or amend any Company Plan, Parent Plan or any other employee benefit plan, program or arrangement of any kind or (ii) limit the right of the Parent, the Company, the Surviving Corporation or any of their respective Subsidiaries to amend, merge or terminate any Post-Effective Plan, Company Plan or Parent Plan.

Section 6.14 [Obligations of Merger Sub.](#)

(a) If required by applicable Law and the Organizational Documents of Merger Sub, Merger Sub will promptly after the execution of this Agreement and in any event no later than 11:59 p.m., Eastern time, on the date of this Agreement, submit this Agreement to Merger Sub's stockholder for the purpose of approving the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated by this Agreement, including the Merger, by written consent (the "[Merger Sub Approval](#)"), and Merger Sub shall use its commercially reasonable efforts to obtain the Merger Sub Approval as promptly as reasonably practicable after the date of execution of this Agreement and in any event no later than 11:59 p.m., Eastern time, on the date of this Agreement.

(b) Merger Sub agrees that: (i) its board of directors shall unanimously recommend that its sole stockholder or sole member, as the case may be, vote to adopt and approve (or consent in writing to the adoption and approval of) this Agreement and the Merger and shall use commercially reasonable efforts to solicit such approval within the applicable time set forth in [Section 6.14\(a\)](#).

Section 6.15 [Tax Matters.](#)

(a) Notwithstanding anything herein to the contrary, none of the Company, Parent or Merger Sub shall take, or omit to take, any action that would, or could reasonably be expected to, prevent or impede the Merger from qualifying for the Intended Tax Treatment. Prior to the Effective Time, Parent and the Company shall use their commercially reasonable efforts, and shall cause their respective Subsidiaries to use their commercially reasonable efforts, to take or cause to be taken any action necessary for the Merger to qualify for the Intended Tax Treatment. This Agreement is intended to constitute, and the Parties hereby adopt this Agreement as, a "plan of reorganization" within the meaning of Treasury Regulation Section 1.368-2(g) and 1.368-3(a). Each of Parent and the Company shall report the Merger consistent with the Intended Tax Treatment, in which no gain or loss is recognized by Parent, the Company, Parent's stockholders, the holders of Company Capital Stock, the Company, or Merger Sub, unless otherwise required pursuant to a "determination" within the meaning of Section 1313(a) of the Code.

(b) If, in connection with the preparation and filing of the Registration Statement or any other filing required by applicable Law or the SEC's review thereof, the SEC requires that a tax opinion with respect to the U.S. federal income tax consequences of the Merger be prepared and submitted, the Parties shall cooperate and use their respective reasonable best efforts to obtain any Tax opinions required to be filed with the SEC in connection with the filing of the Registration Statement or any other filings with the SEC, including delivering to the applicable counsel representation letters necessary or appropriate to enable applicable counsel to issue a Tax opinion, subject to customary assumptions and limitations, in connection with any filings with the SEC, dated and executed as of the date the Registration Statement shall have been declared effective by the SEC or such other date(s) as determined necessary by counsel in connection with any such filings or exhibits. For the avoidance of doubt, in no event shall any such Tax opinion be a condition to Closing.

Section 6.16 FIRPTA Certificate. On or no more than thirty (30) days prior to the Closing Date, the Company shall provide Parent with (i) a certificate (in form and substance reasonably satisfactory to Parent) in accordance with Treasury Regulations Section 1.1445-2(c)(3) stating that it is not and has not been a U.S. real property holding corporation (as defined in Section 897(c)(2) of the Code) during the applicable period specified in Section 897(c) of the Code, (ii) an accompanying notice pursuant to Treasury Regulations Section 1.897-2(h)(2) and (iii) proof of mailing of such notice and certificate to the IRS.

Section 6.17 Allocation Certificate.

(a) The Company will prepare and deliver to Parent at least seven (7) Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of the Company in a form reasonably acceptable to Parent setting forth (as of immediately prior to the Effective Time) (a) each holder of Company Common Stock (assuming the Preferred Stock Conversion and Notes Conversion), Company Options, and Company Warrants, (b) such holder's name and address, (c) the number of shares of Company Common Stock held by each such holder and/or underlying the Company Options and Company Warrants as of such time, and (d) the number of shares of Parent Common Stock to be issued to such holder, or to underlie any Parent Option or Parent Warrant to be issued to such holder, pursuant to this Agreement in respect of the shares of Company Common Stock, Company Options, Company Warrants and Company Convertible Notes held by such holder as of immediately prior to the Effective Time (the "Allocation Certificate").

(b) Parent will prepare and deliver to the Company at least seven (7) Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of Parent in a form reasonably acceptable to the Company setting forth (as of immediately prior to the Effective Time) the number of outstanding shares of Parent Common Stock (the "Parent Outstanding Equity Certificate").

Section 6.18 Legends. Parent shall be entitled to place appropriate legends on the book entries and/or certificates evidencing any shares of Parent Common Stock to be received in the Merger by equity holders of the Company who may be considered "affiliates" of Parent for purposes of Rules 144 and 145 promulgated under the Securities Act reflecting the restrictions set forth in such Rules 144 and 145 and to issue appropriate stop transfer instructions to the transfer agent for Parent Common Stock.

Section 6.19 Parent and Surviving Corporation Directors and Officers. Each of Parent and the Company shall use commercially reasonable efforts and take all necessary action so that immediately after the Effective Time:

(a) (i) the Parent Board is comprised of seven (7) members, with two (2) such members designated by Parent and five (5) such members designated by the Company prior to the Closing, and (ii) the Persons listed in Exhibit D under the heading “Parent Officers” are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time. If any such Person listed in Exhibit D is unable or unwilling to serve as an officer of Parent, as set forth therein, as of the Effective Time, Parent and the Company shall mutually agree upon a substitute individual prior to the Closing. The Persons listed in Exhibit D under the heading “Board Designees – Parent” shall be Parent’s designees pursuant to clause (i) of this Section 6.19 (which list may be changed by Parent at any time prior to the Closing by written notice to the Company to include different board designees who are reasonably acceptable to the Company) (the “Parent Designees”). The Persons listed in Exhibit D under the heading “Board Designees – Company” shall be the Company’s designees pursuant to clause (i) of this Section 6.19 (which list may be changed by the Company at any time prior to the Closing by written notice to Parent to include different board designees who are reasonably acceptable to Parent). Prior to the Closing, (i) the Company shall use commercially reasonable efforts to obtain the written resignation, in a form reasonably satisfactory to Parent, dated as of the Closing Date and effective as of the Effective Time, executed by each of the officers and directors of the Company listed on Exhibit D under the heading “Resigning Company Officers and Directors” and (ii) Parent shall use commercially reasonable efforts to obtain the written resignation, in a form reasonably satisfactory to the Company, dated as of the Closing Date and effective as of the Effective Time, executed by each of the officers and directors of Parent listed on Exhibit D under the heading “Resigning Parent Officers and Directors.”

(b) (i) the Persons listed in Exhibit D under the heading “Surviving Corporation Directors” are appointed to the positions of directors of Surviving Corporation, to serve in such positions effective as of the Effective Time, and (ii) the Persons listed in Exhibit D under the heading “Surviving Corporation Officers” are elected or appointed, as applicable, to the positions of officers of Surviving Corporation, as set forth therein, to serve in such positions effective as of the Effective Time. If any such Person listed in Exhibit D is unable or unwilling to serve as a director or officer of Surviving Corporation, as set forth therein, as of the Effective Time, Parent and the Company shall mutually agree upon a substitute individual prior to the Closing.

Section 6.20 Termination of Certain Agreements. The Company shall cause any Investor Agreements to be terminated immediately prior to the Effective Time, without any liability being imposed on the part of Parent, the Surviving Corporation or any of their respective Subsidiaries.

Section 6.21 Section 16 Matters. Prior to the Effective Time, Parent and the Company shall take all such steps as may be required (to the extent permitted under applicable Law) to cause any acquisitions of Parent Common Stock and any options to purchase Parent Common Stock in connection with the transactions contemplated by this Agreement, by each individual who is reasonably expected to become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent, to be exempt under Rule 16b-3 promulgated under the Exchange Act. At least five (5) Business Days prior to the Closing Date, the Company shall furnish the following information to Parent for each individual who, immediately after the Effective Time, will become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent: (a) the number of shares of Company Common Stock owned by such individual and expected to be exchanged for shares of Parent Common Stock pursuant to the Merger, and (b) the number of other derivative securities (if any) with respect to shares of Company Common Stock owned by such individual and expected to be converted into shares of Parent Common Stock or derivative securities with respect to Parent Common Stock in connection with the Merger.

Section 6.22 Company Financial Statements.

(a) To the extent not already provided to Parent as of the date of this Agreement, as promptly as reasonably practicable following the date hereof, the Company will furnish to Parent (i) audited financial statements for the fiscal years ended December 31, 2021 and December 31, 2022, for inclusion in the Proxy Statement and the Registration Statement (the “Company Audited Financial Statements”) and (ii) unaudited interim financial statements for each interim period completed prior to Closing that would be required to be included in the Proxy Statement, the Registration Statement or any periodic report due prior to the Closing if the Company were subject to the periodic reporting requirements under the Securities Act or the Exchange Act (the “Company Interim Financial Statements”). Each of the Company Audited Financial Statements and the Company Interim Financial Statements will be suitable for inclusion in the Proxy Statement and Registration Statement and prepared in accordance with GAAP as applied on a consistent basis during the periods involved (except in each case as described in the notes thereto) and on that basis will present fairly, in all material respects, the financial position and the results of operations, changes in stockholders’ equity, and cash flows of the Company as of the dates of and for the periods referred to in the Company Audited Financial Statements or the Company Interim Financial Statements, as the case may be. The Company Audited Financial Statements shall have been audited in accordance with the standards of the Public Company Accounting Oversight Board.

(b) The Company shall reasonably cooperate with Parent and its accounting advisors in order to enable Parent to reasonably promptly determine whether such Party is or would be required to include pro forma financial statements related to the transactions contemplated by this Agreement for any periods prior to Closing in the reports to be filed by Parent with the SEC pursuant to the Securities Act or the Exchange Act, including the Proxy Statement, the Registration Statement and any other document related thereto. Such cooperation shall include providing to Parent and its accounting advisors reasonably promptly such financial information concerning the Company and its Subsidiaries as Parent may reasonably request and facilitating reasonable access to the Company’s accountants and employees of the Company and its Subsidiaries with related knowledge thereof in connection therewith.

(c) To the extent not audited as of the date of this Agreement, the Company shall, at the Company’s sole expense, cause a nationally recognized independent public accounting firm reasonably acceptable to Parent to complete an audit for the Company’s consolidated financial statements for the fiscal year ended December 31, 2022, as soon as practicable following the date of this Agreement meeting the requirements set forth in Section 6.22(a) (the date the audits are so completed, the “Audit Completion Date”). Upon completion of the audit, the Company shall deliver a true and complete copy of such audited financial statements to Parent, together with the audit opinion thereon. The Company shall keep Parent reasonably informed as to the status and any material developments with respect to the audit.

Section 6.23 Stockholder Litigation.

(a) Parent shall conduct and control the settlement and defense of any stockholder litigation against Parent or any of its directors or officers relating to this Agreement or the transactions contemplated by this Agreement; provided that any change in counsel advising Parent or any of its directors or officers with respect to such litigation, settlement or other resolution of any such stockholder litigation agreed to by Parent after the Effective Time shall be approved in advance by a majority of the Parent Designees for so long as any Parent Designees are still members of the Parent Board. Without limiting the foregoing, prior to the Effective Time, the Company shall have the opportunity to consult with Parent in connection with the defense and settlement of any such stockholder litigation, and Parent shall keep the Company reasonably apprised of any material developments in connection with any such stockholder litigation.

(b) The Company shall conduct and control the settlement and defense of any stockholder litigation against the Company or any of its directors or officers relating to this Agreement or the transactions contemplated by this Agreement. Without limiting the foregoing, prior to the Effective Time, the Company shall give Parent the opportunity to consult with the Company in connection with the defense and settlement of any such stockholder litigation, and the Company shall keep Parent reasonably apprised of any material developments in connection with any such stockholder litigation.

Section 6.24 Calculation of Parent Net Cash.

(a) Section 6.24(a) of the Parent Disclosure Letter sets forth Parent's good faith estimate of Parent Net Cash and the components thereof, calculated as if the Closing had occurred on March 27, 2023. The Parties agree that Parent Net Cash, including for purposes of the Parent Net Cash Schedule, will be calculated based on the same assumptions and methodologies used in preparing Section 6.24(a) of the Parent Disclosure Letter.

(b) On or prior to the Determination Date, Parent shall deliver the Parent Net Cash Schedule to the Company. Upon the reasonable request of the Company, Parent shall make the work papers and back-up materials used or useful in preparing the Parent Net Cash Schedule available to the Company and, as reasonably requested by the Company, Parent's accountants and counsel at reasonable times and upon reasonable notice. Within three (3) Business Days after Parent delivers the Parent Net Cash Schedule to the Company (the "Parent Net Cash Response Date"), subject to the terms and definitions of this Agreement, the Company will have the right to dispute any part of such Parent Net Cash Schedule by delivering a written notice to that effect to Parent (a "Company Dispute Notice"). Any Company Dispute Notice shall identify in reasonable detail the nature of any proposed revisions to the calculation of Parent Net Cash set forth in the Parent Net Cash Schedule. If on or prior to the Parent Net Cash Response Date, (i) the Company notifies Parent in writing that it has no objections to the Parent Net Cash Schedule or (ii) the Company fails to deliver a Company Dispute Notice, then Parent Net Cash as set forth in the Parent Net Cash Schedule shall be deemed to have been finally determined for purposes of this Agreement and to represent the Parent Net Cash at the Anticipated Closing Date for purposes of this Agreement. If the Company delivers a Company Dispute Notice on or prior to the Parent Net Cash Response Date, then members of senior management of Parent and the Company, and their applicable Representatives, shall promptly meet in person or telephonically at mutually agreed upon times and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of Parent Net Cash, which agreed upon Parent Net Cash amount shall be deemed to have been finally determined for purposes of this Agreement and to represent the Parent Net Cash at the Anticipated Closing Date for purposes of this Agreement.

(c) If the Company delivers a Company Dispute Notice on or prior to the Parent Net Cash Response Date and Parent and the Company are unable to negotiate an agreed-upon determination of Parent Net Cash at the Anticipated Closing Date pursuant to [Section 6.24\(b\)](#), within three (3) calendar days after delivery of the Company Dispute Notice, then, in either case, Deloitte & Touche LLP or another nationally recognized independent public accounting firm mutually agreed upon by Parent and the Company (the “[Accounting Firm](#)”) shall be engaged to resolve any remaining disagreements as to the determination of Parent Net Cash at the Anticipated Closing Date, Parent and the Company shall use commercially reasonable efforts to cause the Accounting Firm to make its determination within ten (10) calendar days of accepting its engagement. Parent shall promptly deliver to the Accounting Firm the work papers and back-up materials used or useful in preparing the Parent Net Cash Schedule. Each of Parent and the Company shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; provided that the other Party is provided with the opportunity to attend any such presentations or discussions. The Accounting Firm shall be bound by the assumptions and methodologies used in preparing [Section 6.24\(a\)](#) of the Parent Disclosure Letter (in determining Parent Net Cash), and the determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm. Such determination by the Accounting Firm shall be final and binding for purposes of this Agreement on the Parties. The Parties shall delay the Closing until two (2) Business Days after the resolution of the matters described in this [Section 6.24\(c\)](#). The fees and expenses of the Accounting Firm shall be allocated between Parent and the Company in the same proportion that the disputed amount of Parent Net Cash that was unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total disputed amount of Parent Net Cash. If this [Section 6.24\(c\)](#) applies, upon resolution of the determination of Parent Net Cash in accordance with this [Section 6.24\(c\)](#), the Parties shall not be required to re-new such determination again even though the Closing Date may occur later than the Anticipated Closing Date, except that either Party may request a re-determination if the Closing Date is more than five (5) Business Days after the Anticipated Closing Date.

Section 6.25 [Permitted Asset Disposition](#). Parent shall be entitled, but under no obligation, to sell, transfer, license, assign or otherwise divest the Potentially Transferable Assets to one or more third parties in one or a series of transactions prior to or concurrently with the Closing; provided, that any such Permitted Asset Disposition shall require, to the extent consistent with applicable Laws, the written consent of the Company, not to be unreasonably withheld, conditioned or delayed, if such Permitted Asset Disposition would create any post-disposition material liabilities for Parent following the Closing. Each Party acknowledges that Parent may not be successful in completing, or may determine not to proceed with, any Permitted Asset Dispositions. For clarity, if the Permitted Asset Dispositions are not completed prior to, concurrently with, or immediately following the Closing, the Potentially Transferable Assets shall be retained by Parent.

Section 6.26 Investor Presentations. Prior to the Closing, each of Parent and the Company shall, and shall use its commercially reasonable efforts to cause their respective Representatives to, reasonably cooperate with the other Party as requested by Parent or the Company, as applicable, in connection with the production of any (i) public statement or other public communication regarding the transactions contemplated by this Agreement or the business of Parent and the Surviving Corporation after the Effective Time or (ii) investor presentation that will be provided or disclosed publicly to stockholders or to any potential investors with respect to any prospective post-Closing financing to which the Parties shall mutually agree to pursue. No Party shall be required, under the provisions of this Section 6.26 or otherwise in connection with any such financing, (i) to provide pro forma financial statements or information, (ii) (A) to provide any cooperation that unreasonably interferes with the ongoing business of such Party or (B) to provide or disclose any information that would (1) in its good faith opinion, result in a violation of applicable Law or a loss of attorney-client or other privilege, (2) breach any obligation of confidentiality to any Third Person, or (3) in the discretion of such Party, is proprietary or competitively sensitive. In no event shall Parent or the Company be in breach of this Agreement because of the failure to deliver any financial or other information that is not currently readily available to such Party on the date of this Agreement or is not otherwise prepared in the ordinary course of business of such Party at the time requested by the other Party.

ARTICLE VII CONDITIONS PRECEDENT

Section 7.1 Conditions to Each Party's Obligation to Effect the Merger. The obligation of each Party to effect the Merger is subject to the satisfaction or, to the extent permitted by applicable Law, waiver at or prior to the Closing of the following conditions:

(a) Approvals. The Company Stockholder Approval and the Parent Stockholder Approval shall each have been obtained.

(b) No Injunctions or Legal Restraints; Illegality. No temporary restraining order, preliminary or permanent injunction or other Order issued by any court of competent jurisdiction or other legal restraint or prohibition shall be in effect, and no Law shall have been enacted, entered, promulgated, enforced or deemed applicable by any Governmental Entity that, in any such case, prohibits or makes illegal the consummation of either Merger, the Parent Stock Issuance or the other transactions contemplated by this Agreement.

(c) Registration Statement. The Registration Statement shall have been declared effective by the SEC under the Securities Act and no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been initiated or threatened.

(d) Nasdaq Listing. (i) The existing shares of Parent Common Stock shall have been continually listed on Nasdaq as of and from the date of this Agreement through the Closing Date, (ii) the shares of Parent Common Stock to be issued in the Merger pursuant to this Agreement shall have been approved for listing, subject to official notice of issuance, on Nasdaq after the Closing, and (iii) to the extent required by Nasdaq Marketplace Rule 5110, the Nasdaq Listing Application has been approved for listing (subject to official notice of issuance).

Section 7.2 Conditions to the Obligations of Parent and Merger Sub. The obligations of Parent and Merger Sub to effect the Merger are also subject to the satisfaction, or, to the extent permitted by applicable Law, waiver by Parent, at or prior to the Closing of the following conditions:

(a) Representations and Warranties. (i) Each of the representations and warranties of the Company set forth in Section 4.1(a), Section 4.2(a) (other than de minimis inaccuracies), Section 4.4, Section 4.5(a)(i) and Section 4.24 shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date as if made as of the Closing Date (except to the extent such representations and warranties expressly relate to an earlier date, in which case as of such earlier date); and (ii) each of the remaining representations and warranties of the Company set forth in this Agreement shall be true and correct as of the date of this Agreement and as of the Closing Date as though made as of the Closing Date (except to the extent such representations and warranties expressly relate to an earlier date, in which case as of such earlier date), except for inaccuracies of representations or warranties the circumstances giving rise to which, individually or in the aggregate, have not had and would not reasonably be expected to have a Company Material Adverse Effect (it being understood that, for purposes of determining the accuracy of such representations and warranties, all materiality and “Company Material Adverse Effect” qualifications and exceptions contained in such representations and warranties shall be disregarded).

(b) Performance of Obligations of the Company. The Company shall have performed or complied in all material respects all obligations required to be performed or complied by it under this Agreement at or prior to the Closing.

(c) Officers’ Certificate. Parent shall have received a certificate signed by the Chief Executive Officer or Chief Financial Officer of the Company certifying (i) as to the matters set forth in Section 7.2(a), Section 7.2(b) and Section 7.2(d) and (ii) that the information set forth in the Allocation Certificate delivered by the Company in accordance with Section 6.17 is true and accurate in all respects as of the Closing Date.

(d) Absence of Company Material Adverse Effect. Since the date of this Agreement there shall not have occurred any Company Material Adverse Effect.

(e) Conversion of Securities. Subject to only the occurrence of the Effective Time, the Preferred Stock Conversion and the Notes Conversion shall have been completed, in accordance with Section 3.1(f) and Section 3.1(g), respectively, such that as of the Effective Time no shares of Company Preferred Stock or Company Convertible Notes shall be outstanding.

(f) NIA Funding. The Company shall have delivered to Parent evidence reasonably satisfactory to Parent that the Company's funding mechanism awarded from the National Institute of Aging is in effect.

(g) Company Lock-Up Agreements. The Lock-up Agreements for the parties set forth on Section A-2 of the Company Disclosure Letter will continue to be in full force and effect as of immediately following the Effective Time.

(h) Termination of Investor Agreements. The Investor Agreements shall have been terminated.

Section 7.3 Conditions to the Obligations of the Company. The obligation of the Company to effect the Merger is also subject to the satisfaction, or, to the extent permitted by applicable Law, waiver by the Company, at or prior to the Closing of the following conditions:

(a) Representations and Warranties. (i) Each of the representations and warranties of Parent set forth in Section 5.1(a), Section 5.2(a) (other than de minimis inaccuracies), Section 5.4, Section 5.5(a)(i) and Section 5.23 shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date as if made as of the Closing Date (except to the extent such representations and warranties expressly relate to an earlier date, in which case as of such earlier date); and (ii) each of the remaining representations and warranties of the Company set forth in this Agreement shall be true and correct as of the date of this Agreement and as of the Closing Date as though made as of the Closing Date (except to the extent such representations and warranties expressly relate to an earlier date, in which case as of such earlier date), except for inaccuracies of representations or warranties the circumstances giving rise to which, individually or in the aggregate, have not had and would not reasonably be expected to have a Parent Material Adverse Effect (it being understood that, for purposes of determining the accuracy of such representations and warranties, all materiality and "Parent Material Adverse Effect" qualifications and exceptions contained in such representations and warranties shall be disregarded).

(b) Performance of Obligations of Parent and Merger Sub. Each of Parent and Merger Sub shall have performed or complied in all material respects all obligations required to be performed or complied by it under this Agreement at or prior to the Closing.

(c) Officers' Certificate. The Company shall have received a certificate signed by the Chief Executive Officer or Chief Financial Officer of Parent certifying as to (i) the matters set forth in Section 7.3(a), Section 7.3(b) and Section 7.3(d) and (ii) that the information set forth in the Allocation Certificate delivered by the Company in accordance with Section 6.17 is true and accurate in all respects as of the Closing Date.

(d) Absence of Parent Material Adverse Effect. Since the date of this Agreement there shall not have occurred any Parent Material Adverse Effect.

(e) Minimum Parent Net Cash. Parent shall have a minimum of \$12,000,000 of Parent Net Cash, as set forth in the Parent Net Cash Schedule and determined in accordance with Section 6.24.

(f) Resignations; Removals. Written resignations in forms satisfactory to the Company, dated as of the Closing Date, executed by the officers and directors of Parent and any Subsidiary who are not to continue as officers or directors of Parent or any of its Subsidiaries pursuant to Section 6.19 or the removal of such officers and directors of Parent and its Subsidiaries.

(g) Board of Directors. Parent shall have caused the Parent Board to be constituted as set forth in Section 6.19 of this Agreement, effective as of the Effective Time.

(h) Parent Lock-Up Agreements. The Parent Lock-Up Agreements for the parties set forth on Section A-2 of the Parent Disclosure Letter will continue to be in full force and effect as of immediately following the Effective Time.

(i) Sarbanes-Oxley Certification. Neither the principal executive officer nor the principal financial officer of Parent shall have failed to provide, with respect to any Parent SEC Document filed (or required to be filed) with the SEC on or after the date of this Agreement, any required certification in the form required under Rule 13a-14 under the Exchange Act and 18 U.S.C. §1350.

Section 7.4 Frustration of Closing Conditions. (a) Parent may not rely on the failure of any condition set forth in Section 7.2 to be satisfied if such failure was proximately caused by any action or failure to act of Parent that constitutes a breach of this Agreement by Parent and (b) the Company may not rely on the failure of any condition set forth in Section 7.3 to be satisfied if such failure was proximately caused by any action or failure to act of the Company that constitutes a breach of this Agreement by the Company.

ARTICLE VIII TERMINATION, AMENDMENT AND WAIVER

Section 8.1 Termination. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time (unless otherwise specified below, whether before or after the Company Stockholder Approval or the Parent Stockholder Approval has been obtained):

(a) by mutual written consent of Parent and the Company;

(b) by either Parent or the Company:

(i) if the Merger shall not have been consummated on or before August 31, 2023 (the "Outside Date"); provided, that the right to terminate this Agreement pursuant to this Section 8.1(b)(i) shall not be available to Parent or the Company, as applicable, if such Party's (or, in the case of Parent, Merger Sub's) failure to fulfill in any material respect any of its obligations under this Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated by the Outside Date, unless such failure was primarily caused by the other Party's breach of any of its obligations under this Agreement, provided, further, that, in the event that the SEC has not declared the Registration Statement effective under the Securities Act by the date which is thirty (30) calendar days prior to the Outside Date, then Parent or the Company shall be entitled to extend the Outside Date for an additional sixty (60) calendar days by written notice to the other Party; or

(ii) if any court of competent jurisdiction or other Governmental Entity shall have issued an Order or taken any other Action restraining, enjoining or otherwise prohibiting any of the transactions contemplated by this Agreement and such Order or other Action shall have become final and nonappealable; provided, that the right to terminate this Agreement pursuant to this [Section 8.1\(b\)\(ii\)](#) shall not be available to Parent or the Company, as applicable, if such Party's failure to fulfill in any material respect any of its obligations under this Agreement has been the cause of, or resulted in, such Order or other Action, unless such failure was primarily caused by the other Party's breach of any of its obligations under this Agreement;

(c) by Parent, if the Company Stockholder Approval shall not have been obtained and evidence thereof delivered to Parent in accordance with [Section 6.5\(a\)](#); provided, however, that once the Company Stockholder Approval has been obtained, Parent may not terminate this Agreement pursuant to this [Section 8.1\(c\)](#);

(d) by Parent or the Company, if the Parent Stockholder Approval shall not have been obtained at the Parent Stockholders' Meeting duly convened therefor or, if the Parent Stockholders' Meeting has been postponed or adjourned, at the final adjournment or postponement thereof, at which a vote on the adoption of this Agreement was taken; provided, that Parent shall not be permitted to terminate this Agreement pursuant to this [Section 8.1\(d\)](#) if the failure to fulfill in any material respect any of its obligations under this Agreement has been the cause of, or resulted in, the Parent Stockholder Approval not being obtained, unless such failure was primarily caused by the Company's breach of any of its obligations under this Agreement;

(e) by Parent, if the Company shall have breached or failed to perform any of its representations, warranties, covenants or agreements set forth in this Agreement, or if any representation or warranty of the Company shall have become untrue, which breach or failure to perform or to be true, either individually or in the aggregate, if occurring or continuing at the Effective Time (A) would result in the failure of any of the conditions set forth in [Section 7.1](#) or [Section 7.2](#) and (B) cannot be or, if curable, has not been cured by the earlier of (1) the Outside Date and (2) ten (10) days after the giving of written notice to the Company of such breach or failure; provided, that Parent shall not have the right to terminate this Agreement pursuant to this [Section 8.1\(e\)](#) if the failure to fulfill in any material respect any of Parent's obligations under this Agreement has been the cause of, or resulted in, the Company's breach, unless such failure was primarily caused by the Company's breach of any of its obligations under this Agreement; or

(f) by the Company:

(i) if Parent shall have breached or failed to perform any of its representations, warranties, covenants or agreements set forth in this Agreement, or if any representation or warranty of Parent shall have become untrue, which breach or failure to perform or to be true, either individually or in the aggregate, if occurring or continuing at the Effective Time (i) would result in the failure of any of the conditions set forth in [Section 7.1](#) or [Section 7.3](#) and (ii) cannot be or, if curable, has not been cured by the earlier of (A) the Outside Date and (B) ten (10) days after the giving of written notice to Parent of such breach or failure; provided, that the Company shall not have the right to terminate this Agreement pursuant to this [Section 8.1\(f\)\(i\)](#) if the failure to fulfill in any material respect any of the Company's obligations under this Agreement has been the cause of, or resulted in, the Parent's breach, unless such failure was primarily caused by Parent's material breach of any of its obligations under this Agreement;

(ii) prior to receipt of the Parent Stockholder Approval, if: (A) a Parent Adverse Recommendation Change shall have occurred, (B) a Parent Triggering Event shall have occurred, or (C) Parent or any then director or officer of Parent shall have Willfully Breached [Section 6.3](#) of this Agreement; or

(g) by Parent, prior to receipt of the Parent Stockholder Approval, if the Parent Board authorized Parent to enter into an Alternative Acquisition Agreement; provided however, that Parent shall not enter into any Alternative Acquisition Agreement unless (i) Parent has materially complied with its obligations under [Section 6.3](#) and (ii) Parent concurrently pays to the Company the amount required by [Section 8.3\(c\)](#), if required to do so by [Section 8.3\(c\)](#).

(h) by the Company, if at any time after the date of this Agreement and prior to the Closing, Parent Net Cash (as calculated in accordance with this Agreement) has fallen below \$12,000,000 such that the condition to Closing in [Section 7.3\(e\)](#) would not be satisfied as of the Closing Date and such deficiency is not reasonably capable of being cured prior to the Closing Date.

The Party desiring to terminate this Agreement pursuant to this [Section 8.1](#) (other than pursuant to [Section 8.1\(a\)](#)) shall give written notice of such termination to the other party.

Section 8.2 [Effect of Termination](#). In the event of termination of this Agreement, this Agreement shall immediately become void and have no effect, without any liability or obligation on the part of any Party, provided, that:

(a) the Confidential Disclosure Agreement and the provisions of this [Section 8.2](#), [Section 8.3](#) (Fees and Expenses), [Section 9.2](#) (Notices), [Section 9.5](#) (Entire Agreement), Section 9.6 (No Third-Party Beneficiaries), [Section 9.7](#) (Governing Law), [Section 9.8](#) (Submission to Jurisdiction), [Section 9.9](#) (Assignment; Successors), [Section 9.10](#) (Specific Performance), [Section 9.12](#) (Severability), [Section 9.13](#) (Waiver of Jury Trial) and [Section 9.15](#) (No Presumption Against Drafting Party) shall survive the termination hereof;

(b) the Company or Parent and Merger Sub may have liability as provided in [Section 8.3](#); and

(c) subject to [Section 8.3\(e\)](#), no such termination shall relieve any party from any liability or damages resulting from a Willful Breach of any of its representations, warranties, covenants or agreements set forth in this Agreement or a Fraud Claim, in which case the non-breaching party shall be entitled to all rights and remedies available at Law or in equity.

Section 8.3 Fees and Expenses.

(a) Except as set forth in this [Section 8.3](#), [Section 6.10\(d\)](#), [Section 6.11](#) and [Section 6.24](#), all fees and expenses incurred in connection with this Agreement and the transactions contemplated by this Agreement shall be paid by the Party incurring such expenses, whether or not the Merger is consummated. It is understood and agreed that (i) all fees and expenses incurred or to be incurred by the Company in connection with the transactions contemplated by this Agreement and preparing, negotiating and entering into this Agreement and the performance of its obligations under this Agreement shall be paid by the Company in cash at or prior to the Closing, (ii) all fees and expenses incurred or to be incurred by Parent in connection with the transactions contemplated by this Agreement and preparing, negotiating and entering into this Agreement and the performance of its obligations under this Agreement shall be paid by Parent in cash at or prior to the Closing and (iii) certain fees and expenses may be allocated differently for purposes of calculating Parent Net Cash as set forth in the respective definitions thereof.

(b) If (i)(A) this Agreement is validly terminated by Parent or the Company pursuant to [Section 8.1\(d\)](#) or (B) this Agreement is validly terminated by the Company pursuant to [Section 8.1\(b\)\(i\)](#) or [Section 8.1\(f\)\(i\)](#), (ii) at any time after the date of this Agreement and prior to the Parent Stockholder Meeting, a Parent Acquisition Proposal shall have been publicly announced, disclosed or otherwise communicated to Parent or the Parent Board (which Parent Acquisition Proposal shall not have been withdrawn) and (iii) within twelve (12) months after the date of such termination, Parent enters into an Alternative Acquisition Agreement for the Parent Acquisition Proposal referred to in clause (ii) (which is subsequently consummated) or consummates a transaction in respect of the Parent Acquisition Proposal referred to in clause (ii), then Parent shall pay to the Company a nonrefundable fee in an amount equal to \$765,000 (the "[Company Termination Fee](#)") upon such consummation or entry into an Alternative Acquisition Agreement, as the case may be; provided, that solely for purposes of this [Section 8.3\(b\)](#), all references in the term Parent Acquisition Proposal to "twenty percent (20%) or more" shall be deemed to be references to "fifty percent (50%) or more" and all references to "less than eighty percent (80%)" shall be deemed to be references to "less than fifty percent (50%)"; provided further, that if Parent does not timely receive applicable wire instructions from the Company prior to the payment deadline, then the Company Termination Fee will instead be payable within two (2) Business Days of Parent's receipt from the Company of such wire instructions.

(c) If (i) this Agreement is validly terminated by Parent pursuant to [Section Section 8.1\(g\)](#), Parent shall pay to the Company, concurrent with such termination, the Company Termination Fee or (ii) this Agreement is validly terminated by the Company pursuant to [Section 8.1\(f\)\(ii\)](#), Parent shall pay to the Company, within two (2) Business Days of the date of such termination, the Company Termination Fee; provided, however, that if Parent does not timely receive applicable wire instructions from the Company prior to the payment deadline, then such amount will instead be payable within two (2) Business Days of Parent's receipt from the Company of such wire instructions.

(d) Any Company Termination Fee due under this [Section 8.3](#) shall be paid by wire transfer of same day funds to an account designated in writing by the Company to Parent. If Parent fails to pay when due any amount payable by it under this [Section 8.3](#), and in order to obtain such payment the Company commences a suit that results in a judgment against Parent for such payment then (i) Parent shall reimburse the Company for reasonable and documented out-of-pocket costs and expenses (including reasonable fees and disbursements of counsel) incurred in connection with the such suit, and (ii) Parent shall pay to the Company interest on such overdue amount (for the period commencing as of the date such overdue amount was originally required to be paid and ending on (but excluding) the date such overdue amount is actually paid to the Company in full) at a rate per annum equal to the “prime rate” (as published in *The Wall Street Journal* or any successor thereto) in effect on the date such overdue amount was originally required to be paid.

(e) The Parties agree that, notwithstanding anything in this Agreement to the contrary but subject to [Section 8.2\(a\)](#), payment of the Company Termination Fee shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of the Company and the Company Related Parties against Parent, Merger Sub and any Parent Related Party following the termination of this Agreement, it being understood that in no event shall Parent be required to pay the amounts payable pursuant to [Section 8.3\(b\)](#) or [Section 8.3\(c\)](#) on more than one occasion and (ii) following payment of the Company Termination Fee, (x) none of Parent, Merger Sub or any Parent Related Party shall have any further liability to the Company in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by Parent or Merger Sub giving rise to such termination, or the failure of the transactions contemplated by this Agreement to be consummated, (y) neither the Company nor any of the Company Related Parties shall be entitled to bring or maintain any other claim, action or proceeding against Parent, Merger Sub or any Parent Related Party) or seek to obtain any recovery, judgment or damages of any kind against Parent, Merger Sub or any Parent Related Party in connection with or arising out of this Agreement or the termination thereof, any breach by any such Persons giving rise to such termination or the failure of the transactions contemplated by this Agreement to be consummated and (z) the Company and the Company Related Parties shall be precluded from any other remedy against Parent, Merger Sub and the Parent Related Parties, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such party giving rise to such termination or the failure of the transactions contemplated by this Agreement to be consummated; provided, however, that nothing in this [Section 8.3\(f\)](#) shall limit the rights of the Company under [Section 9.10](#). Each of the Parties acknowledges that (i) the agreements contained in [Section 8.3\(b\)](#) and [Section 8.3\(c\)](#) are an integral part of the transactions contemplated by this Agreement, (ii) without this agreement, the Parties would not enter into this Agreement and (iii) any amount payable pursuant to [Section 8.3\(b\)](#) or [Section 8.3\(c\)](#), as the case may be, is not a penalty, but rather is liquidated damages in a reasonable amount that will compensate the Company in the circumstances in which such amount is payable.

Section 8.4 [Amendment or Supplement](#). This Agreement may be amended, modified or supplemented by Parent and the Company by action taken or authorized by their respective Boards of Directors at any time prior to the Effective Time, whether before or after Parent Stockholder Approval has been obtained; provided, however, that after the Parent Stockholder Approval has been obtained, no amendment shall be made that pursuant to applicable Law requires further approval or adoption by the stockholders of Parent without such further approval or adoption. This Agreement may not be amended, modified or supplemented in any manner, whether by course of conduct or otherwise, except by an instrument in writing specifically designated as an amendment hereto, signed on behalf of each of Parent and the Company at the time of such amendment.

Section 8.5 Extension of Time; Waiver. At any time prior to the Effective Time, Parent and the Company may, by action taken or authorized by their respective Boards of Directors, to the extent permitted by applicable Law, (a) extend the time for the performance of any of the obligations or acts of the other Parties, (b) waive any inaccuracies in the representations and warranties of the other Parties set forth in this Agreement or any document delivered pursuant hereto or (c) subject to applicable Law, waive compliance with any of the agreements or conditions of the other Parties contained herein; provided, however, that after the Parent Stockholder Approval has been obtained, no waiver shall be made that pursuant to applicable Law requires further approval or adoption by the stockholders of Parent without such further approval or adoption. Any agreement on the part of a Party to any such waiver shall be valid only if set forth in a written instrument executed and delivered by a duly authorized officer on behalf of such Party. No failure or delay of any Party in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such right or power, or any course of conduct, preclude any other or further exercise thereof or the exercise of any other right or power. The rights and remedies of the Parties hereunder are cumulative and are not exclusive of any rights or remedies which they would otherwise have hereunder.

ARTICLE IX GENERAL PROVISIONS

Section 9.1 Non-survival of Representations and Warranties. None of the representations, warranties, covenants or agreements in this Agreement or in any certificate or other instrument delivered pursuant to this Agreement shall survive the Effective Time, other than those covenants or agreements of the Parties which by their terms apply, or are to be performed in whole or in part, after the Effective Time.

Section 9.2 Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly given (a) on the date of delivery if delivered personally, or if by e-mail, when sent (provided that no “error message” or other notification of non-delivery is generated), (b) on the first Business Day following the date of dispatch if delivered utilizing a next-day service by a recognized next-day courier or (c) on the earlier of confirmed receipt or the third (3rd) Business Day following the date of mailing if delivered by registered or certified mail, return receipt requested, postage prepaid. All notices hereunder shall be delivered to the addresses set forth below, or pursuant to such other instructions as may be designated in writing by the Party to receive such notice:

- (i) if to Parent or Merger Sub, to:

Diffusion Pharmaceuticals Inc.
300 East Main Street, Suite 201
Charlottesville, VA
Attention: Robert J. Cobuzzi, Jr., Ph.D.
William R. Elder
E-mail: rcobuzzi@diffusionpharma.com
welder@diffusionpharma.com

with a copy (which shall not constitute notice) to:

Dechert LLP
1095 Avenue of the Americas
New York, New York 10036
Attention: David S. Rosenthal
 John E. Alessi
E-mail: david.rosenthal@dechert.com
 john.alessi@dechert.com

(ii) if to the Company, to:

EIP Pharma, Inc.
20 Park Plaza, Suite 424
Boston, Massachusetts 02116
Attention: John Alam
E-mail: jalam@eippharma.com

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: William C. Hicks
 Scott M. Stanton
 Jason S. McCaffrey
E-mail: wchicks@mintz.com
 smstanton@mintz.com
 jsmccaffrey@mintz.com

Section 9.3 Certain Definitions. For purposes of this Agreement:

(a) “Acceptable Confidentiality Agreement” means an executed confidentiality agreement containing terms (including a “standstill” provision that prohibits the making of an Acquisition Proposal to Parent (other than an Acquisition Proposal to Parent on a confidential, non-public basis)), in the aggregate, that are not less favorable in the aggregate to Parent than those contained in the Confidential Disclosure Agreement and that shall not prohibit compliance by Parent with Section 6.3.

(b) “Accounting Firm” has the meaning set forth in Section 6.24(e).

(c) “Accredited Holder” means any holder of Company Capital Stock that has properly completed and duly executed and delivered to Parent a Company Stockholder Support Agreement certifying in accordance with such agreement that such holder is an “accredited investor” for the purposes of, and within the meaning of Rule 501(a) of, Regulation D promulgated under the Securities Act.

(d) “Action” has the meaning set forth in [Section 4.10](#).

(e) “Affiliate” of any Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person. The term “control” (including the terms “controlled by” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities, by contract or otherwise.

(f) “Agreement” has the meaning set forth in the preamble.

(g) “Allocation Certificate” has the meaning set forth in [Section 6.17\(a\)](#).

(h) “Alternative Acquisition Agreement” means any acquisition agreement, merger agreement or similar agreement (other than an Acceptable Confidentiality Agreement) with respect to a Parent Acquisition Proposal.

(i) “Anticipated Closing Date” means the anticipated Closing Date (as mutually agreed in good faith by Parent and the Company).

(j) “Applicable Company Shares” has the meaning set forth in [Section 3.3\(b\)](#).

(k) “Business Day” means any day other than a Saturday, a Sunday or a day on which banks in New York, New York are authorized or required by applicable Law to be closed.

(l) “Cash and Cash Equivalents” means all (i) cash and cash equivalents (excluding restricted cash) and (ii) marketable securities.

(m) “Certificate” has the meaning set forth in [Section 3.3\(b\)](#).

(n) “Certificate of Merger” has the meaning set forth in [Section 2.3](#).

(o) “Chosen Courts” has the meaning set forth in [Section 9.8](#).

(p) “Closing” has the meaning set forth in [Section 2.2](#).

(q) “COBRA” has the meaning set forth in [Section 4.13\(c\)\(iv\)](#).

(r) “Commercially Available Software” means commercially available software that has not been modified or customized by a Third Person for a Party and that is licensed pursuant to a non-negotiated agreement, and for which a Party or its Subsidiaries pay less than \$100,000 in licensing or other fees per software title per annum.

(s) “Company” has the meaning set forth in the Preamble.

(t) “Company Acquisition Proposal” means any proposal or offer from a Third Person with respect to any direct or indirect acquisition or purchase or license, in one transaction or a series of transactions, and whether through any merger, reorganization, consolidation, contribution, tender offer, exchange offer, stock acquisition, asset acquisition, binding share exchange, business combination, recapitalization, liquidation, dissolution, joint venture, licensing, sale-leaseback or similar transaction, or otherwise, (A) of assets or businesses of the Company and its Subsidiaries that generate twenty percent (20%) or more of the consolidated net revenues or net income (for the twelve (12)-month period ending on the last day of the Company’s most recently completed fiscal quarter) or that represent twenty percent (20%) or more of the total assets (based on fair market value) of the Company and its Subsidiaries, taken as a whole, immediately prior to such transaction, (B) of twenty percent (20%) or more of any class of capital stock, other equity securities or voting power of the Company, any of its Subsidiaries or any resulting parent company of the Company, in each case other than the Merger and other transactions contemplated by this Agreement, or (C) pursuant to which the members of the Company immediately prior to the consummation of such transaction hold less than eighty percent (80%) of the equity interests of the surviving or resulting entity of such transaction.

(u) “Company Board” has the meaning set forth in the Recitals.

(v) “Company Board Recommendation” has the meaning set forth in [Section 4.4\(b\)](#).

(w) “Company Capital Stock” means the Company Common Stock and the Company Preferred Stock.

(x) “Company Change of Control Payment” has the meaning set forth in [Section 4.17\(a\)\(vi\)](#).

(y) “Company Common Stock” means the common stock, \$0.001par value per share, of the Company.

(z) “Company Convertible Notes” means those certain (i) Convertible Promissory Notes of the Company, dated as of December 4, 2021, in the aggregate principal amount of \$5,078,500, and (ii) Convertible Promissory Notes of the Company, dated as of December 10, 2021, in the aggregate principal amount of \$6,000,000.

(aa) “Company Data” means all data and information, including Personal Information, whether in electronic or any other form or medium, that is accessed, collected, used, processed, stored, shared, distributed, transferred, disclosed, destroyed, or disposed of or otherwise held by or on behalf of the Company, the Parent, or any of their respective Subsidiaries, as applicable.

- (bb) “Company Disclosure Letter” has the meaning set forth in Article IV.
- (cc) “Company Dispute Notice” has the meaning set forth in Section 6.24(d).
- (dd) “Company Equity Plan” means the EIP Pharma, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan.
- (ee) “Company Audited Financial Statements” has the meaning set forth in Section 6.22(a).
- (ff) “Company Financial Statements” has the meaning set forth in Section 4.6(a).
- (gg) “Company Inquiry” has the meaning set forth in Section 6.2(a).
- (hh) “Company Interim Financial Statements” has the meaning set forth in Section 6.12(a).
- (ii) “Company Material Adverse Effect” has the meaning set forth in Section 4.1(a).
- (jj) “Company Material Contract” has the meaning set forth in Section 4.17(a).
- (kk) “Company Option” has the meaning set forth in Section 3.2(a).
- (ll) “Company Owned IP” means all Intellectual Property owned or purported to be owned by the Company or any of its Subsidiaries in whole or in part.
- (mm) “Company Plan” has the meaning set forth in Section 4.13(a).
- (nn) “Company Preferred Stock” means the preferred stock, \$0.001 par value per share, of the Company.
- (oo) “Company Real Property Leases” has the meaning set forth in Section 4.19(b).
- (pp) “Company Registered IP” has the meaning set forth in Section 4.20(a).
- (qq) “Company Related Party” means a Non-Recourse Party with respect to the Company.
- (rr) “Company Stockholder Approval” has the meaning set forth in Section 4.4(a).
- (ss) “Company Stockholder Letter” means a stockholder qualification letter substantially in the form attached as Schedule B to the Company Stockholder Support Agreement containing certifications by the undersigned stockholder that such holder is an “accredited investor” for the purposes of, and within the meaning of Rule 501(a) of, Regulation D promulgated under the Securities Act.

- (tt) “Company Stockholder Support Agreement” has the meaning set forth in the Recitals.
- (uu) “Company Stockholder Written Consent” has the meaning set forth in the Recitals.
- (vv) “Company Termination Fee” has the meaning set forth in Section 8.3(b).
- (ww) “Company Transaction Related Expenses” means Transaction Related Expenses of the Company or any of its Subsidiaries.
- (xx) “Company Unregistered IP” has the meaning set forth in Section 4.20(a).
- (yy) “Company Warrant” means warrants exercisable for Company Common Stock.
- (zz) “Confidential Disclosure Agreement” has the meaning set forth in Section 6.6(d).
- (aaa) “Continuation Period” has the meaning set forth in Section 6.13(a).
- (bbb) “Continuing Employees” has the meaning set forth in Section 6.13(b).
- (ccc) “Contract” means any legally binding bond, debenture, note, mortgage, indenture, guarantee, license, lease, purchase or sale order or other contract, commitment, agreement, instrument, obligation, arrangement, understanding, undertaking, Permit, concession or franchise, whether oral or written (including all amendments thereto).
- (ddd) “Control” (including the terms “controlled,” and “controlled by”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by Contract or otherwise.
- (eee) “Data Security Breach” means any accidental or unlawful unauthorized access to, acquisition of, disclosure, use, loss, denial or loss of use, alteration, destruction, compromise, or unauthorized Processing of Company Data, including Personal Information, in the possession or control of the Company, the Parent, or any of their Subsidiaries, as applicable, or any other act or omission that compromises the security, integrity, or confidentiality of information, including Personal Information.
- (fff) “D&O Related Claim” has the meaning set forth in Section 6.10(a).

(ggg) “Delaware Secretary of State” has the meaning set forth in Section 2.3.

(hhh) “Determination Date” means the date that is ten (10) days prior to the Anticipated Closing Date.

(iii) “DFA” has the meaning set forth in Section 4.12(c).

(jjj) “DGCL” has the meaning set forth in Recitals.

(kkk) “Dissenting Shares” has the meaning set forth in Section 3.5.

(lll) “Effective Time” has the meaning set forth in Section 2.3.

(mmm) “Enforceability Exception” has the meaning set forth in Section 4.4(a).

(nnn) “Environmental Law” has the meaning set forth in Section 4.15(b).

(ooo) “Environmental Permits” has the meaning set forth in Section 4.15(a).

(ppp) “ERISA” has the meaning set forth in Section 4.13(a).

(qqq) “ERISA Affiliate” means any Person, trade or business, whether or not incorporated, that, together with any Person, is (or, to the extent any Person has any ongoing liability with respect thereto, was) a member of a controlled group of organizations required to be treated as a single employer for purposes of Section 414 of the Code or Section 4001 of ERISA.

(rrr) “Exchange Act” means the Securities Exchange Act of 1934.

(sss) “Exchange Agent” has the meaning set forth in Section 3.3(a).

(ttt) “Exchange Fund” has the meaning set forth in Section 3.3(a).

(uuu) “Exchange Ratio” means, subject to Section 3.1, the following ratio (rounded to four decimal places): the quotient obtained by dividing (a) the Company Merger Shares by (b) the Company Outstanding Shares, in which:

- “Company Allocation Percentage” means 1.00 minus the Parent Allocation Percentage.

- “Company Merger Shares” means a number of shares equal to (i) the Post-Closing Parent Shares minus (ii) the Parent Outstanding Shares.

- “Company Outstanding Shares” means the total number of shares of Company Capital Stock outstanding immediately prior to the Effective Time expressed on a fully-diluted and as-converted to Company Common Stock basis and assuming, without limitation or duplication, (i) the cashless exercise of all Company Options outstanding as of immediately prior to the Effective Time with an exercise price less than the Parent Closing Price (on a converted to Company Common stock basis) and (ii) the issuance of shares of Company Capital Stock in respect of all warrants, restricted stock units or other similar rights to receive such shares (assuming cashless exercise using the Parent Closing Price (on a converted to Company Common Stock basis), whether conditional or unconditional and including any outstanding warrants, restricted stock units or other similar rights (including the Company Convertible Notes, any other convertible notes and accrued interest in connection therewith and any accrued dividends on Company Capital Stock) triggered by or associated with the consummation of the Merger (but excluding any shares of Company Common Stock reserved for issuance). For the avoidance of doubt, (i) no out-of-the-money Company Options shall be included in the total number of shares of Company Capital Stock outstanding for purposes of determining the Company Outstanding Shares and (ii) the Company Outstanding Shares shall include any shares issued or issuable in respect of the Preferred Stock Conversion.

- “Parent Allocation Percentage” means 0.2275 *provided, however*, to the extent that the Parent Net Cash determined pursuant to Section 6.24 (i) is less than \$13,500,000, then 0.2275 shall be reduced by 0.0005 for each \$100,000 that the Parent Net Cash as so determined is less than \$13,500,000 (for example, the Parent Allocation Percentage would be 0.2225 if the Parent Net Cash determined pursuant to Section 6.24 is \$12,500,000) and (ii) is more than \$14,500,000, then 0.2275 shall be increased by 0.0005 for each \$100,000 that the Parent Net Cash as so determined is more than \$14,500,000 (for example, the Parent Allocation Percentage would be 0.2325 if the Parent Net Cash determined pursuant to Section 6.24 is \$15,500,000).

- “Parent Outstanding Shares” means the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time expressed on a fully-diluted basis and assuming, without limitation or duplication, (i) with respect to Parent Options and Parent Warrants, the cashless exercise solely of those Parent Options and Parent Warrants outstanding as of immediately prior to the Effective Time with an exercise price less than the Parent Closing Price (and otherwise disregarding any other Parent Options and Parent Warrants), (ii) the settlement of each Parent RSU that is outstanding immediately prior to the Effective Time for an equivalent number of shares of Parent Common Stock and (iii) the issuance of shares of Parent Common Stock in respect of all other warrants, restricted stock units or other similar rights to receive such shares (assuming cashless exercise using the Parent Closing Price in the case of warrants and other similar rights), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Parent Common Stock reserved for issuance), in each case after giving effect to the Parent Reverse Split (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application). For the avoidance of doubt, (i) no out-of-the-money Parent Options or Parent Warrants shall be included in the total number of shares of Parent Common Stock outstanding for purposes of determining the Parent Outstanding Shares and (ii) any shares issued in connection with an equity financing permitted pursuant to Section 6.1(b)(ii) shall be included in the total number of shares of Parent Common Stock outstanding for purposes of determining the Parent Outstanding Shares.

• “Post-Closing Parent Shares” means the quotient (rounded to the nearest whole share) determined by dividing (i) the Parent Outstanding Shares by (ii) the Parent Allocation Percentage.

(vvv) “Excluded Shares” has the meaning set forth in [Section 3.1\(b\)](#).

(www) “FDA” means the U.S. Food and Drug Administration or any successor agency thereto.

(xxx) “FDCA” has the meaning set forth in [Section 4.12\(a\)](#).

(yyy) “Fraud Claim” means, with respect to any Party to this Agreement, a claim by any other Party against such first Party for common law liability under Delaware law for its actual and intentional fraud with respect to the making of representations and warranties pursuant to [Article IV](#) (in the case of the Company) or [Article V](#) (in the case of Parent or Merger Sub) (or any certificate delivered pursuant to [Section 7.2\(c\)](#) or [Section 7.3\(c\)](#), but solely in respect of such representations or warranties); provided such actual and intentional fraud of such party shall only be deemed to exist if such party itself (and not any other Person on its behalf (including any agents, representatives or Affiliates (or any employees of any of the foregoing)) of such party) makes a knowing and intentional misrepresentation of a material fact with respect to the making of a representation in [Article IV](#) or [Article V](#), as the case may be, with the intent that the other party rely on such fact, coupled with such other party’s detrimental reliance on such fact under circumstances that constitute common law fraud under applicable Law. For the avoidance of doubt, for the purposes of this Agreement, “Fraud Claim” shall exclude any claims for equitable fraud, constructive fraud, reckless fraud or negligent fraud.

(zzz) “Governmental Entity” means any supranational, national, federal, state, provincial, county, municipal, local or foreign or other government, any instrumentality, subdivision, court or other tribunal, administrative agency, or commission, or other governmental authority, or any quasi-governmental or private body exercising any regulatory or other governmental or quasi-governmental authority and any self-regulatory organization (including Nasdaq).

(aaaa) “Hazardous Substance” has the meaning set forth in [Section 4.15\(c\)](#).

(bbbb) “Indebtedness” means, as of a specified date, collectively, with respect to the Company or Parent, without duplication, the sum of all amounts immediately prior to the Closing owing by such Person and its Subsidiaries with respect to all (a) indebtedness for borrowed money of such Person and its Subsidiaries and all obligations evidenced by bonds, debentures, notes or other similar instruments, (b) obligations under letters of credit, bankers’ acceptances, surety or performance bonds, bank guarantees or similar facilities, (c) cash obligations owed under any lease agreements, including property and equipment lease agreements, (d) purchase money obligations, conditional sale obligations, obligations under any title retention agreements and all other obligations relating to deferred purchase price for property, assets, securities or services (which excludes trade payables incurred in the ordinary course of business), including any “earnout,” contingent consideration or similar payments constituting acquisition consideration to the extent required to be shown as a balance sheet liability in accordance with GAAP and solely to the extent earned in accordance with the underlying definitive acquisition documentation and then due and payable, (e) all obligations of such Person and its Subsidiaries under any interest rate, currency swap, hedging or other derivative transactions, (f) any obligation of such Person and its Subsidiaries in respect of any Taxes the payment or remittance of which was deferred pursuant to the CARES Act or any similar COVID-19 Measures that remains unpaid as of such date, (g) all declared and unpaid distributions of such Person, (h) an amount equal to a prorated portion (based on the number of days elapsed in 2023 through such date) of the annual bonuses of employees of such Person and its Subsidiaries in respect of 2023 determined based on bonus accruals in the ordinary course consistent with past practice and pursuant to the terms of any applicable Company Plans or Parent Plans, as applicable, (i) the amount of any underfunded obligation of such Person and its Subsidiaries under any defined benefit pension, deferred compensation or retiree medical, dental, vision or life insurance plan, and (j) the amount of severance due to any Relevant Service Provider whose employment or other service was terminated or who received or provided a notice of termination, in any case, at any time prior to such date, including, in each case, accrued and unpaid interest on any of the foregoing and any breakage costs, penalties, additional interest, premiums, fees and other costs and expenses associated with prepayment or redemption of any of the foregoing.

(cccc) “Indemnification Party” has the meaning set forth in [Section 6.10\(a\)](#).

(dddd) “Indemnification Period” has the meaning set forth in [Section 6.10\(a\)](#).

(eeee) “Intellectual Property” means all intellectual property rights of any kind or nature in any jurisdiction throughout the world, including all of the following to the extent protected by applicable Law: (i) trademarks or service marks (whether registered or unregistered), trade names, domain names, social media user names, social media addresses, logos, slogans, and trade dress, including applications to register any of the foregoing, together with the goodwill symbolized by any of the foregoing; (ii) patents, utility models and any similar or equivalent statutory rights with respect to the protection of inventions, and all applications for any of the foregoing, together with all re-issuances, continuations, continuations-in-part, divisionals, revisions, extensions and reexaminations thereof; (iii) copyrights (registered and unregistered) and applications for registration; (iv) trade secrets and customer lists, in each case to the extent any of the foregoing derives economic value (actual or potential) from not being generally known to other Persons who can obtain economic value from its disclosure or use, and other confidential information (“Trade Secrets”); and (v) any other proprietary or intellectual property rights of any kind or nature.

(ffff) “Intended Tax Treatment” has the meaning set forth in the Recitals.

(gggg) “IRS” has the meaning set forth in [Section 4.13\(a\)](#).

(hhhh) “IT Systems” has the meaning set forth in [Section 4.20\(e\)](#).

(iiii) “Knowledge” of any Party means (i) with respect to the Company or any of its Subsidiaries, the actual knowledge of each of the individuals listed in [Section 9.3\(iii\)](#) of the Company Disclosure Letter; and (ii) with respect to Parent or any of its Subsidiaries, the actual knowledge of each of the individuals listed in [Section 9.3\(iii\)](#) of the Parent Disclosure Letter; in each case of (i) and (ii), after reasonable inquiry.

(jjjj) “Law” means any federal, state, local or foreign law (including common law), statute, ordinance, rule, code, regulation, Order or other legally enforceable requirement enacted, issued, adopted, promulgated, enforced, ordered, or applied by any Governmental Entity having applicable jurisdiction (including under the authority of Nasdaq or the Financial Industry Regulatory Authority).

(kkkk) “Letter of Transmittal” has the meaning set forth in [Section 3.3\(b\)](#).

(llll) “Lien” means any charge, mortgage, pledge, security interest, lien, purchase agreement, option, restriction on transfer of title or voting, title retention or similar agreement or other encumbrances, other than securities transfer restrictions that customarily arise under securities Laws.

(mmmm) “Lock-Up Agreements” has the meaning set forth in the Recitals.

(nnnn) “Measurement Date” has the meaning set forth in [Section 4.2\(a\)](#).

(oooo) “Merger” has the meaning set forth in the Recitals.

(pppp) “Merger Consideration” has the meaning set forth in [Section 3.1\(a\)](#).

(qqqq) “Merger Sub” has the meaning set forth in the preamble.

(rrrr) “Merger Sub Approval” has the meaning set forth in [Section 6.14\(a\)](#).

(ssss) “Merger Sub Board” has the meaning set forth in the Recitals.

(tttt) “Nasdaq” means the Nasdaq Stock Market, including the Nasdaq Capital Market or such other Nasdaq market on which shares of Parent Common Stock are then listed.

(uuuu) “Nasdaq Listing Application” has the meaning set forth in [Section 6.11\(a\)](#).

(vvvv) “Non-Recourse Party” means, with respect to a Party to this Agreement, any of such Party’s former, current and future equity holders, controlling persons, directors, officers, employees, agents, representatives, Affiliates, members, managers, general or limited partners, financing sources, successors, heirs, beneficiaries or assignees (or any former, current or future equity holder, controlling person, director, officer, employee, agent, representative, Affiliate, member, manager, general or limited partner, financing sources, successors, heirs, beneficiaries or assignee of any of the foregoing).

(wwww) “Notes Conversion” has the meaning set forth in [Section 3.1\(g\)](#).

(xxxx) “Order” means any judgment, ruling, order, writ, injunction, award or decree of any Governmental Entity or arbitrator.

(yyyy) “Organizational Document” means any charter, certificate of formation, certificate of incorporation, articles of organization, declaration of partnership, articles of association, bylaws, operating agreement, limited liability company agreement, partnership agreement or similar formation or governing documents and instruments of any Person.

(zzzz) “Permitted Asset Disposition” means a disposition of any of Parent’s rights in a Potentially Transferable Asset, including, without limitation, any intellectual property rights, data, regulatory documentation, permits or inventory, consummated (or pursuant to an agreement entered into) prior to the Effective Time in accordance with [Section 6.25](#).

(aaaa) “Parent” has the meaning set forth in the preamble.

(bbbb) “Parent Acquisition Proposal” means any proposal or offer from a Third Person with respect to any direct or indirect acquisition or purchase or license, in one transaction or a series of transactions, and whether through any merger, reorganization, consolidation, contribution, tender offer, exchange offer, stock acquisition, asset acquisition, binding share exchange, business combination, recapitalization, liquidation, dissolution, joint venture, licensing, sale-leaseback or similar transaction, or otherwise, (A) of assets or businesses of Parent and its Subsidiaries that generate twenty percent (20%) or more of the consolidated net revenues or net income (for the twelve (12)-month period ending on the last day of Parent’s most recently completed fiscal quarter) or that represent twenty percent (20%) or more of the total assets (based on fair market value) of Parent and its Subsidiaries, taken as a whole, immediately prior to such transaction, in each case other than with respect to a Permitted Asset Disposition, (B) of twenty percent (20%) or more of any class of capital stock, other equity securities or voting power of Parent, any of its Subsidiaries or any resulting parent company of Parent, in each case other than the transactions contemplated by this Agreement, or (C) pursuant to which the stockholders of Parent immediately prior to the consummation of such transaction hold less than eighty percent (80%) of the equity interests of the surviving or resulting entity of such transaction.

(cccc) “Parent Adverse Recommendation Change” means the Parent Board or a committee thereof: (i) withdrawing (or modifying or qualifying in any manner adverse to the Company) the Parent Board Recommendation, (ii) within five (5) Business Days of a tender or exchange offer for shares of Parent Common Stock having been commenced that would have the effect of precluding the Merger, failing to publicly recommend against such tender or exchange offer, (iii) failing to include in the Proxy Statement that is mailed to Parent’s stockholders the Parent Board Recommendation, (iv) approving or otherwise declaring advisable, or recommending the approval by the Parent stockholders of, any Parent Acquisition Proposal, (v) other than in the context of a tender or exchange offer for shares of Parent Common Stock, failing to publicly reaffirm (if so requested by the Company) the Parent Board Recommendation after the date any Parent Acquisition Proposal or any material modification thereto (which request shall only be made once per Parent Acquisition Proposal or material modification) is first publicly announced, within five (5) Business Days after a request to do so by the Company.

(ddddd) “Parent Audited Financial Statements” means the audited consolidated balance sheets of Parent and its Subsidiaries as of December 31, 2020, December 31, 2021 and December 31, 2022 and the related audited consolidated statements of operation, comprehensive loss, members’ equity and cash flows for the fiscal year or relevant period ended December 31, 2020, December 31, 2021 and December 31, 2022, respectively, together with all of the related notes and schedules thereto, accompanied by the reports thereon of Parent’s independent auditors.

(eeee) “Parent Board” has the meaning set forth in the Recitals.

(ffff) “Parent Change of Control Payment” has the meaning set forth in [Section 5.17\(a\)\(vi\)](#).

(ggggg) “Parent Closing Price” means the volume weighted average closing trading price of a share of Parent Common Stock on Nasdaq for the five (5) consecutive trading days ending five (5) trading days immediately prior to the date upon which the Effective Time occurs.

(hhhhh) “Parent Common Stock” has the meaning set forth in the Recitals.

(iiii) “Parent Continuing Employee” has the meaning set forth in [Section 6.13\(a\)](#).

(jjjj) “Parent D&O Tail Policy” has the meaning set forth in [Section 6.10\(d\)](#).

(kkkkk) “Parent Designees” has the meaning set forth in [Section 6.19\(a\)](#).

(llll) “Parent Disclosure Letter” has the meaning set forth in [Article V](#).

(mmmmm) “Parent Dispute Notice” has the meaning set forth in [Section 6.24\(b\)](#).

(nnnnn) “Parent Equity Plan” means the Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended.

(oooo) “Parent Inquiry” has the meaning set forth in [Section 6.3\(a\)](#).

(ppppp) “Parent Intervening Event” means a material fact, event, change, development or circumstance that was not known or reasonably foreseeable to the Parent Board prior to Parent’s execution of this Agreement, which fact, event, change, development or circumstance, or any material consequence thereof, becomes known to the Parent Board after the date of this Agreement and prior to the receipt of the Parent Stockholder Approval, which fact, event, change, development or circumstance is material to Parent and does not relate to (A) a Parent Acquisition Proposal, inquiry or the consequences thereof, (B) the announcement, pendency or consummation of the Merger or any actions required to be taken pursuant to this Agreement, (C) the fact, in and of itself, that Parent meets or exceeds internal budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations, or (D) any change in the price of Parent Common Stock (it being acknowledged that any underlying cause of any change in the price of Parent Common Stock may be taken into account for purposes of determining whether a Parent Intervening Event has occurred for purposes of this clause (D)).

(qqqqq) “Parent IT Systems” has the meaning set forth in Section 5.20(e)(i).

(rrrrr) “Parent Material Adverse Effect” has the meaning set forth in Section 5.1(a).

(sssss) “Parent Material Contract” has the meaning set forth in Section 5.17(a).

(ttttt) “Parent Net Cash” means (A) Parent’s and its Subsidiaries’ Cash and Cash Equivalents as of the Anticipated Closing Date, determined in a manner consistent with the manner in which such items were determined in the Parent Audited Financial Statements, minus (B) the sum of (without duplication) of: (i) Parent’s and its Subsidiaries’ accounts payable and accrued expenses (including accrued tax liabilities, Parent Transaction Related Expenses, unpaid fees and expenses incurred with respect to Parent’s audit of its consolidated financial statements for the fiscal year ended December 31, 2022 and actual unpaid wind-down costs associated with discontinued clinical trials and lab, R&D and related operations, if any) and Parent’s and its Subsidiaries’ other current liabilities payable in cash, in each case as of the Anticipated Closing Date and determined in a manner consistent with the manner in which such items were determined in the Parent Audited Financial Statements (except to the extent such amounts are non-cash liabilities with respect to individuals offered employment as Continuing Employees or who will otherwise be continuing to provide services to Parent or any of its Subsidiaries following the Effective Time). Notwithstanding the foregoing, Parent Net Cash shall be increased by an amount equal to the sum of (without duplication): (1) Parent’s and its Subsidiaries’ accounts receivable, deposits and prepaid expenses (including prepaid premiums for directors’ and officers’ insurance, if any, or any credit due to Parent or any of its Subsidiaries arising from the early termination of Parent’s existing insurance policies the value of which is reasonably expected to be realized by the Surviving Company) and the pre-paid public company expenses listed or described on Section A-3 of the Parent Disclosure Letter), (2) any out of pocket fees and expenses incurred by Parent or any of its Subsidiaries after the date of this Agreement and prior to the Effective Time in connection with actions taken at the written request of the Company other than pursuant to, and in accordance with, this Agreement, (3) any out of pocket fees and expenses, if any, incurred by Parent or any of its Subsidiaries pursuant to the last sentence of Section 6.10(d), if applicable, (4) fifty percent (50%) of the aggregate amount of all fees and expenses incurred by Parent and its Subsidiaries in connection with the filing and mailing, as applicable, of the Registration Statement and the Proxy Statement, (5) fifty percent (50%) of the Parent Stockholder Litigation Costs, (6) any cash proceeds from a Permitted Asset Disposition that are not distributed to the stockholders of Parent prior to the Effective Time, and (7) fifty percent (50%) of the aggregate amount of all fees and expenses incurred by Parent and its Subsidiaries in connection with the listing of shares of Parent Common Stock with Nasdaq pursuant to Section 6.11.

(uuuuu) “Parent Net Cash Response Date” has the meaning set forth in Section 6.24(d).

(vvvvv) “Parent Net Cash Schedule” means a written schedule prepared in accordance with Section 6.24(c) and certified by the Chief Financial Officer of Parent, on behalf of Parent and not in his or her personal capacity, setting forth, in reasonable detail, Parent’s good faith estimate of Parent Net Cash as of the Anticipated Closing Date.

(wwwww) “Parent Notice Period” has the meaning set forth in Section 6.3(d)(ii)(A).

(xxxxx) “Parent Option” means an option to acquire Parent Common Stock.

(yyyyy) “Parent Outstanding Equity Certificate” has the meaning set forth in Section 6.17(b).

(zzzzz) “Parent Owned IP” means all Intellectual Property owned or purported to be owned by Parent or any of its Subsidiaries in whole or in part.

(aaaaa) “Parent Plan” has the meaning set forth in Section 5.13.

(bbbbb) “Parent Preferred Stock” has the meaning set forth in Section 5.2.

(ccccc) “Parent Real Property Leases” has the meaning set forth in Section 5.19(a).

(ddddd) “Parent Related Party” means a Non-Recourse Party with respect to Parent.

(eeeee) “Parent Registered IP” has the meaning set forth in Section 5.20(a).

(ffffff) “Parent Reverse Split” means a reverse stock split of all outstanding shares of Parent Common Stock at a reverse stock split ratio mutually agreed to by Parent and the Company that is effected by Parent for the purpose of maintaining compliance with Nasdaq listing standards.

(ggggg) “Parent RSU” has the meaning set forth in Section 5.2.

(hhhhh) “Parent SEC Documents” has the meaning set forth in Section 5.6(a).

(iiiiii) “Parent Stock Issuance” has the meaning set forth in the Recitals.

(jjjjj) “Parent Stockholder Approval” has the meaning set forth in Section 5.4(a).

(kkkkkk) “Parent Stockholder Litigation Costs” means the aggregate amount of any fees, and expenses, including settlement costs and/or reasonable attorney’s fees, incurred in connection with any threatened or actual stockholder litigation arising or resulting from this Agreement or the transactions contemplated by this Agreement and that may be brought in connection with or on behalf of any Parent stockholder’s interest in Parent Common Stock (including all amounts paid or payable up to the retention amount of any insurance policy that is or may cover such costs or expenses and amounts not covered by any such insurance policy), to the extent that such costs or expenses have otherwise reduced Parent Net Cash.

(llllll) “Parent Stockholder Matters” means the approval of (i) the amendment of Parent’s certificate of incorporation to effect the Parent Reverse Split (to the extent Parent and the Company mutually agree is applicable and necessary to meet the requirements, if any, for the Nasdaq Listing Application), (ii) the Parent Stock Issuance and (iii) any other proposals Parent and the Company mutually agree is necessary or desirable to consummate the transactions contemplated by this Agreement.

(mmmmmm) “Parent Stockholders’ Meeting” has the meaning set forth in [Section 6.4\(a\)](#).

(nnnnnn) “Parent Service Provider” means any current or former director, officer, employee or other individual service provider of Parent or any of its Subsidiaries.

(oooooo) “Parent Stock Issuance” means the issuance, on the terms and subject to the conditions set forth in this Agreement, of the shares of Parent Common Stock or other securities of Parent that represent (or are convertible into) more than twenty percent (20%) of the shares of Parent Common Stock outstanding immediately prior to the Merger to the holders of Company Capital Stock, Company Options and Company Warrants in connection with the transactions contemplated by this Agreement and the change of control of Parent resulting from the transactions contemplated by this Agreement, in each case pursuant to the Nasdaq rules.

(pppppp) “Parent Transaction Related Expenses” means Transaction Related Expenses of Parent or any of its Subsidiaries which for avoidance of doubt shall include the payments set forth on [Section 9.3\(pppppp\)](#) of the Parent Disclosure Schedule.

(qqqqqq) “Parent Triggering Event” shall be deemed to have occurred if: (i) Parent shall have failed to include in the Proxy Statement the Parent Board Recommendation or shall have made a Parent Adverse Recommendation Change; (ii) the Parent Board or any committee thereof shall have approved, endorsed or recommended any Acquisition Proposal; or (iii) Parent shall have entered into any letter of intent or similar document or any Contract relating to any Acquisition Proposal (other than a confidentiality agreement permitted pursuant to the terms of this Agreement).

(rrrrrr) “Parent Registered IP” has the meaning set forth in [Section 5.20\(a\)](#).

(ssssss) “Parent Unregistered IP” has the meaning set forth in [Section 5.20\(a\)](#).

(tttttt) “Parent Warrants” has the meaning set forth in [Section 5.2](#).

(uuuuuu) “Party” or “Parties” has the meaning set forth in the preamble.

(vvvvvv) “Payor” has the meaning set forth in [Section 3.4](#).

(wwwww) “PBGC” has the meaning set forth in Section 4.13(c)(iii).

(xxxxxx) “Pension Plan” has the meaning set forth in Section 4.13(b).

(yyyyyy) “Permits” has the meaning set forth in Section 4.11.

(zzzzzz) “Permitted Liens” means as to any Person: (i) statutory Liens for current Taxes and assessments not yet past due or the amount or validity of which is being contested in good faith by appropriate proceedings and for which adequate reserves have been established in accordance with GAAP, (ii) mechanics’, workmen’s, repairmen’s, warehousemen’s and carriers’ and similar statutory Liens arising in the ordinary course of business of such Person consistent with past practice, (iii) zoning, entitlement, building, and other land use regulations imposed by Governmental Entities having jurisdiction over such Person’s owned or leased real property, which are not violated by the current use and operation of such real property, (iv) covenants, conditions, restrictions, easements, and other similar non-monetary matters of record affecting title to such Person’s owned or leased real property, which do not materially detract from the value of or materially impair the occupancy or use of such real property for the purposes for which it is currently used in connection with such Person’s businesses; (v) any right of way or easement related to public roads and highways, which do not materially detract from the value of or materially impair the occupancy or use of such real property for the purposes for which it is currently used in connection with such Person’s businesses; (vi) Liens arising under workers’ compensation, unemployment insurance, social security, retirement, and similar legislation; (vii) statutory and contractual Liens to secure obligations to landlords under real property leases; (viii) unrecorded easements, restrictions and similar agreements that do not materially detract from the value of or materially impair the occupancy or use of the affected real property for the purposes for which it is currently used in connection with such Person’s businesses; and (ix) non-exclusive licenses of Intellectual Property granted in the ordinary course of business.

(aaaaaaa) “Person” means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including any Governmental Entity.

(bbbbbbb) “Personal Information” means (i) all information identifying, or that alone or in combination with other information allows for the identification of, an individual; and (ii) any information that is defined as “personal information,” “protected health information,” “personal data” or other similar term under applicable Privacy Laws.

(ccccccc) “Post-Effective Plans” has the meaning set forth in Section 6.13(b).

(ddddddd) “Potentially Transferrable Asset” means the Parent’s product candidates, *trans sodium crocetinate* and DFN-529.

(eeeeeee) “Preferred Stock Conversion” has the meaning set forth in Section 3.1(f).

(ffffff) “Process”, “Processed”, or “Processing” means any operation or set of operations that is performed upon data, including Personal Information, whether or not by automatic means, such as collection, recording, organization, structuring, transfer, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction, or instruction, training or other learning relating to such data or combination of data, including Personal Information.

(ggggggg) “Products” has the meaning set forth in [Section 4.12\(c\)](#).

(hhhhhhh) “Proxy Statement” has the meaning set forth in [Section 5.8](#).

(iiiiiii) “Privacy Agreements” means any contracts, commitments, obligations, or responsibilities to affiliated and unaffiliated third parties, including individuals, governing the Processing of Personal Information, into which any of the Company, the Parent, or any of their respective Subsidiaries, as applicable, has entered or is otherwise bound.

(jjjjjjj) “Privacy Commitments” means any and all: (i) applicable Privacy Laws, (ii) Privacy Policies, (iii) Privacy Agreements, and (iv) applicable published industry best practice or rules of any applicable self-regulatory organizations in which any of the Company, the Parent, or any of their respective Subsidiaries, as applicable, is or has been a member.

(kkkkkkk) “Privacy Laws” means any applicable Law concerning the privacy, security, transfer, or Processing of Personal Information, including, as applicable, Laws with respect to data retention, data disposal, data breach notification, consumer protection, requirements for website and mobile application privacy policies, practices and notices, Social Security number protection, data security, and email, text message, or telephone communications.

(lllllll) “Privacy Policy” means each written statement made by the Company, the Parent, or any of their Subsidiaries, as applicable, related to the Processing of Personal Information, including website or mobile app privacy policies or notices and notices or policies related to the privacy of employees, individual contractors, temporary workers, and job applicants.

(mmmmmmm) “Registration Statement” means the registration statement on Form S-4 (or any other applicable form under the Securities Act to register Parent Common Stock) to be filed with the SEC by Parent registering the public offering and sale of Parent Common Stock to some or all holders of Company Common Stock in the Merger, including all shares of Parent Common Stock to be issued in exchange for all other shares of Company Common Stock in the Merger, as said registration statement may be amended prior to the time it is declared effective by the SEC.

(nnnnnnn) “Regulatory Laws” has the meaning set forth in [Section 4.12\(a\)](#).

(ooooooo) “Release” has the meaning set forth in [Section 4.15\(d\)](#).

(ppppppp) “Relevant Service Provider” means any current or former director, officer, employee or other individual service provider of the Company or any of its Subsidiaries.

(qqqqqq) “Representative” of a Person means, any director, manager, officer, employee, financial advisor, attorney, accountant or other advisor, agent or other representative of that Person.

(rrrrrr) “Requisite Preferred Vote” means the affirmative vote of (A) the holders of a majority of the shares of Series A Preferred Stock, voting as a single class on an as converted basis, and (B) holders of a majority of the shares of Series B Preferred Stock, voting as a single class on an as converted basis.

(ssssss) “Requisite Stockholder Vote” means, collectively, (A) the affirmative vote of holders of a majority of the shares of Company Common Stock (including the shares Company Preferred Stock voting on an as converted basis) and (B) the Requisite Preferred Vote.

(tttttt) “SEC” means the United States Securities and Exchange Commission.

(uuuuuu) “Securities Act” means the Securities Act of 1933.

(vvvvvv) “Security Incident” has the meaning set forth in [Section 5.20\(e\)](#).

(wwwww) “Series A Preferred Stock” has the meaning set forth in [Section 4.2\(a\)](#).

(xxxxxx) “Series A-1 Preferred Stock” has the meaning set forth in [Section 4.2\(a\)](#).

(yyyyyy) “Series A-2 Preferred Stock” has the meaning set forth in [Section 4.2\(a\)](#).

(zzzzzz) “Series B Preferred Stock” has the meaning set forth in [Section 4.2\(a\)](#).

(aaaaaa) “Stockholder Notice” has the meaning set forth in [Section 6.5\(b\)](#).

(bbbbbb) “Subsidiary” means with respect to any Person, any corporation, limited liability company, partnership, association, or other business entity of which (i) if a corporation, a majority of the total voting power of shares of stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers, or trustees thereof is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other subsidiaries of that Person or a combination thereof or (ii) if a limited liability company, partnership, association, or other business entity (other than a corporation), a majority of partnership or other similar ownership interests thereof having the power to govern or elect members of the applicable governing body of such entity is at the time owned or controlled, directly or indirectly, by that Person or one or more subsidiaries of that Person or a combination thereof; and the term “Subsidiary” with respect to any Person shall include all subsidiaries of each subsidiary of such Person.

(ccccc) “Superior Proposal” means any unsolicited bona fide written Parent Acquisition Proposal, that: (i) did not result from a breach of Section 6.3 and (ii) the Parent Board determines in good faith (after consultation with outside counsel and its financial advisor) based on such matters that it deems relevant (including the likelihood of consummation thereof and the financing terms thereof), is more favorable to the stockholders of Parent (in their capacity as such) from a financial point of view than the Merger (including any adjustment to the terms and conditions proposed by the Company in writing in response to such Parent Acquisition Proposal in accordance with Section 6.3(d)) and is not subject to any financing condition (and if financing is required, such financing is fully committed to the Third Person); provided, that, for purposes of this definition of “Superior Proposal,” all references to “twenty percent (20%) or more” shall be deemed to be references to “fifty percent (50%) or more” and all references to “less than eighty percent (80%)” shall be deemed to be references to “less than fifty percent (50%).”

(dddddd) “Surviving Corporation” has the meaning set forth in Section 2.1.

(eeeeee) “Takeover Laws” has the meaning set forth in Section 4.21(b).

(ffffff) “Tax Action” has the meaning set forth in Section 4.16(d).

(gggggg) “Tax Return” means any return, declaration, report, certificate, bill, election, claim for refund, information return, statement or other written information and any other document filed or supplied or required to be filed or supplied to any Governmental Entity or any other Person with respect to Taxes, including any schedule, attachment or supplement thereto, and including any amendment thereof.

(hhhhh) “Taxes” means (i) all federal, state, local, foreign and other net income, gross income, gross receipts, sales, use, stock, ad valorem, transfer, transaction, franchise, profits, gains, registration, license, wages, lease, service, service use, employee and other withholding, social security, unemployment, welfare, disability, payroll, employment, excise, severance, stamp, environmental, occupation, workers’ compensation, premium, real property, personal property, escheat or unclaimed property, windfall profits, net worth, capital, value-added, alternative or add-on minimum, customs duties, estimated and other taxes, fees, assessments, charges or levies of any kind whatsoever in the nature of a tax (whether imposed directly or through withholding and including taxes of any Third Person in respect of which a Person may have a duty to collect or withhold and remit and any amounts resulting from the failure to file any Tax Return), whether disputed or not, together with any interest and any penalties, additions to tax or additional amounts with respect thereto; (ii) any liability for payment of amounts described in clause (i) whether as a result of transferee liability, of being a member of an affiliated, consolidated, combined or unitary group for any period or otherwise through operation of Law; and (iii) any liability for the payment of amounts described in clauses (i) or (ii) as a result of any tax sharing, tax indemnity or tax allocation agreement or any other express or implied agreement to indemnify any other Person.

(iiiiii) “Third Person” means any Person (or “group” as defined pursuant to under Section 13(d) of the Exchange Act) other than the Parties and their respective Affiliates and Representatives acting on such Party’s behalf or, directly or indirectly, at such Party’s direction.

(jjjjjj) “Transaction Related Claim” has the meaning set forth in Section 9.7.

(kkkkkkkk) “Transaction Related Expenses” means as of a specified date, with respect to any Person, the sum of: (i) the cash cost of any change of control payments, retention payments, severance payments, transaction payments or similar payments that are or become due to any current or former employee, officer, director, manager or independent contractor of such Person or any of its Subsidiaries in connection with the consummation of the transactions contemplated by this Agreement and that are unpaid as of such date (plus the employer portion of all employment, unemployment, payroll and similar Taxes payable thereon), but excluding any such amounts with respect to individuals offered employment as Continuing Employees or who will otherwise be continuing to provide services to Parent or any of its Subsidiaries following the Effective Time, (ii) any fees and expenses incurred by such Person or its Subsidiaries, or for which such Person or its Subsidiaries is liable, in connection with the negotiation, preparation and execution of this Agreement and the consummation of the transactions contemplated by this Agreement and that are unpaid as of such date, including brokerage fees and commissions, finders’ fees or financial advisory fees, or any fees and expenses of counsel, accountants or other advisors payable by such Person or its Subsidiaries, (iii) any payments to third parties required under any Contract to which such Person or its Subsidiaries are a party actually triggered by the consummation of the transactions contemplated by this Agreement, or any payment or consideration actually arising under or in relation to any notice to any Third Person or the obtaining of any consents, waivers or approvals of any Third Person under any Contract to which such Person or its Subsidiaries are a party required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, in order for any such Contract to remain in full force and effect following the Closing or resulting from agreed-upon modification or early termination of any such Contract, (iv) any cash payment required to be made to the holder of any existing warrant or similar agreement pursuant to the “fundamental transaction” or similar provision of such existing warrant or similar agreement that are or become due to such holder in connection with the consummation of the transactions contemplated by this Agreement and that are unpaid as of such date, and (v) the premium, if any, for the Parent D&O Tail Policy incurred pursuant to Section 6.10(d) that is unpaid as of such date, if any.

(llllllll) “WARN Act” has the meaning set forth in Section 4.14(d).

(mmmmmmmm) “Willful Breach” means a deliberate act or failure to act, which act or failure to act constitutes in and of itself a material breach of this Agreement, with the actual knowledge that the taking of such action or failure to take such action would constitute or cause a material breach of this Agreement.

Section 9.4 Interpretation. When a reference is made in this Agreement to a Section, Article, Exhibit or Schedule such reference shall be to a Section, Article, Exhibit or Schedule of this Agreement unless otherwise indicated. The table of contents and headings contained in this Agreement or in any Exhibit or Schedule are for convenience of reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein shall have the meaning as defined in this Agreement. All Exhibits and Schedules annexed hereto or referred to herein, and the Company Disclosure Letter and the Parent Disclosure Letter, are hereby incorporated in and made a part of this Agreement as if set forth herein. The word “including” and words of similar import when used in this Agreement will mean “including, without limitation,” unless otherwise specified. The words “hereof,” “herein” and “hereunder” and words of similar import when used in this Agreement shall refer to the Agreement as a whole and not to any particular provision in this Agreement. The term “or” is not exclusive. The word “will” shall be construed to have the same meaning and effect as the word “shall.” If the last day of the time period for the giving of any notice or the taking of any action required under this Agreement falls on a day that is not a Business Day, the time period for giving such notice or taking such action shall be extended through the next Business Day following the original expiration date of such time period. Each reference to any Law, statute, regulation or other governmental rule shall be to such Law, statute, regulation or other governmental rule, respectfully, as amended, modified, codified, replaced or re-enacted, in whole or in part, including rules, regulations, enforcement procedures and any interpretations promulgated thereunder, all as in effect on the date of this Agreement. References to days mean calendar days unless otherwise specified. The Parties agree and acknowledge that for a document to be “made available” to a party hereunder with respect to the representations and warranties in Article IV and Article V means (i) with respect to the Company, that the Company or its Representatives have posted such information or documentation to the “EIP Pharma Clinical and Non-Clinical Due Diligence” and “EIP Pharma Corporate Due Diligence” folders located in the Citrix ShareFile Virtual Data Room and (ii) with respect to Parent, Parent or its Representatives have posted such information or documentation to the “Project Dawn Due Diligence” folder located in the Citrix ShareFile Virtual Data Room, in each case by 11:59 p.m., Eastern Time, on March __, 2023.

Section 9.5 Entire Agreement. This Agreement (including the Exhibits hereto) and the Company Disclosure Letter, the Parent Disclosure Letter, the Confidential Disclosure Agreement, the Company Stockholder Support Agreements, the Parent Stockholder Support Agreements and the Lock-Up Agreements constitute the entire agreement, and supersede all prior written agreements, arrangements, communications and understandings and all prior and contemporaneous oral agreements, arrangements, communications and understandings among the parties with respect to the subject matter hereof and thereof.

Section 9.6 No Third-Party Beneficiaries.

(a) Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person other than the Parties and their respective successors and permitted assigns any legal or equitable right, benefit or remedy of any nature under or by reason of this Agreement, except as provided in Section 6.10.

(b) The representations and warranties in this Agreement are the product of negotiations among the Parties and are for the sole benefit of the Parties. Any inaccuracies in such representations and warranties are subject to waiver by the Parties in accordance with Section 8.5 without notice or liability to any other Person. In some instances, the representations and warranties in this Agreement may represent an allocation among the Parties of risks associated with particular matters regardless of the Knowledge of any of the Parties. Consequently, Persons other than the Parties may not rely upon the representations and warranties in this Agreement as characterizations of actual facts or circumstances as of the date of this Agreement or as of any other date.

Section 9.7 Governing Law. This Agreement and all claims or causes of action based upon, arising out of, or related to this Agreement or any document, certificate or instrument delivered in connection herewith, or the transactions contemplated by this Agreement, including the negotiation, execution or performance of this Agreement (whether in contract, tort or otherwise) (each, a "Transaction Related Claim"), shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to any applicable conflicts of Law principles that would require the application of the substantive Laws of another jurisdiction.

Section 9.8 Submission to Jurisdiction. Each Party agrees that it will bring any action or proceeding in respect of any Transaction Related Claim exclusively in Court of Chancery of the State of Delaware and any state appellate court therefrom within the State of Delaware, or in the event (but only in the event) that such Court of Chancery declines to accept jurisdiction over such action or proceeding, any federal court within the State of Delaware or the Complex Commercial Litigation Division of the Superior Court of the State of Delaware located in New Castle County (the "Chosen Courts"), and, in connection with claims based upon, arising under or related to this Agreement or the transactions that are the subject of this Agreement, (i) irrevocably submits to the exclusive jurisdiction of the Chosen Courts, (ii) waives any objection to laying venue in any such action or proceeding in the Chosen Courts, (iii) waives any objection that the Chosen Courts are an inconvenient forum or do not have jurisdiction over any party and (iv) agrees that service of process upon such party in any such action or proceeding will be effective if notice is given in accordance with Section 9.2.

Section 9.9 Assignment; Successors. Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated, in whole or in part, by operation of law or otherwise, by any Party without the prior written consent of the other Parties, and any such assignment without such prior written consent shall be null and void. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

Section 9.10 Specific Performance. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed by the Parties in accordance with their specific terms or were otherwise breached. It is accordingly agreed that Parent and Merger Sub, on the one hand, and the Company, on the other hand, shall be entitled to an injunction or injunctions to prevent breaches or threatened breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of competent jurisdiction and that this shall include the right of Parent and Merger Sub to cause the Company, on the one hand, and the right of the Company to cause Parent and Merger Sub, on the other hand, to fully perform the terms of this Agreement to the fullest extent permissible pursuant to this Agreement and applicable Law and to thereafter cause this Agreement and the transactions contemplated by this Agreement to be consummated on the terms and subject to the conditions thereto set forth in this Agreement. Such remedies shall be cumulative and not exclusive and shall be in addition to any other remedies which any party may have under this Agreement or otherwise. The parties hereto agree that the right of specific performance and other equitable relief is an integral part of the transactions contemplated by this Agreement and without that right, none of Parent, Merger Sub or the Company would have entered into this Agreement. Each of the Parties hereby waives (i) any defenses in any action for specific performance, including the defense that a remedy at Law would be adequate and agree not to raise any objections to the availability of the equitable remedy of specific performance and (ii) any requirement under any Law to post a bond, surety or other security as a prerequisite to obtaining equitable relief. If any Party brings any action to enforce specifically the performance of the terms and provisions hereof by any other Party, the Outside Date shall be automatically extended for so long as the Party bringing such action is actively seeking a court order for an injunction or injunctions or to specifically enforce the terms and provisions of this Agreement. For the avoidance of doubt, in no event shall the exercise of the right of any Party to seek specific performance pursuant to this Section 9.10 reduce, restrict or otherwise limit the other Parties' right to terminate this Agreement pursuant to Section 8.1 and/or the right of any of Parent, Merger Sub or the Company to pursue all applicable remedies at Law.

Section 9.11 Currency. All references to “dollars” or “\$” in this Agreement refer to United States dollars, which is the currency used for all purposes in this Agreement.

Section 9.12 Severability. Whenever possible, each provision or portion of any provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision or portion of any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable Law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision or portion of any provision in such jurisdiction, and this Agreement shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision or portion of any provision had never been contained herein.

Section 9.13 Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH SUCH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE EXTENT PERMITTED BY LAW AT THE TIME OF INSTITUTION OF THE APPLICABLE LITIGATION, ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT: (A) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, AND (B) EACH PARTY (I) UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (II) MAKES THIS WAIVER VOLUNTARILY, AND (III) EACH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 9.13.

Section 9.14 Counterparts. This Agreement and any signed agreement or instrument entered into in connection with this Agreement may be executed in two or more counterparts, each such counterpart being deemed to be an original instrument and all such counterparts together constituting the same agreement and, to the extent signed and delivered by means of a facsimile machine or telecopy, by email delivery of a “.pdf” or “.jpg” format data file or by any electronic signature complying with the U.S. federal ESIGN Act of 2000, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No party hereto or to any such agreement or instrument shall raise the use of a facsimile machine or telecopy, email delivery of a “.pdf” or “.jpg” format data file or electronic signature complying with the U.S. federal ESIGN Act of 2000 to deliver a signature to this Agreement or any amendment hereto or the fact that any signature or agreement or instrument was transmitted or communicated through the use of a facsimile machine or telecopy, email delivery of a “.pdf” or “.jpg” format data file or by any electronic signature complying with the U.S. federal ESIGN Act of 2000 as a defense to the formation of a contract and each party hereto forever waives any such defense.

Section 9.15 No Presumption Against Drafting Party. Each of Party acknowledges that each other Party to this Agreement has been represented by counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of Law or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the drafting Party has no application and is expressly waived.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

DIFFUSIONS PHARMACEUTICALS INC.

By: /s/ Robert J. Cobuzzi, Jr., Ph.D.
Name: Robert J. Cobuzzi, Jr., Ph.D.
Title: President and Chief Executive Officer

DAWN MERGER SUB INC.

By: /s/ Robert J. Cobuzzi, Jr., Ph.D.
Name: Robert J. Cobuzzi, Jr., Ph.D.
Title: President

EIP PHARMA, INC.

By: /s/ John Alam
Name: John Alam
Title: President and Chief Executive Officer

[Signature Page to Agreement and Plan of Merger]

**CERTIFICATE OF AMENDMENT
OF THE CERTIFICATE OF INCORPORATION (AS AMENDED)
OF
DIFFUSION PHARMACEUTICALS INC.**

DIFFUSION PHARMACEUTICALS INC., a corporation incorporated and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation") does hereby certify:

FIRST: That, at a meeting of the Board of Directors of the Corporation (the "Board of Directors") on March 29, 2023 a resolution was duly adopted setting forth a proposed amendment to the Certificate of Incorporation (as amended) of the Corporation in the form set forth below (the "Amendment"), declaring said Amendment to be advisable and calling for consideration of said proposed Amendment by the stockholders of the Corporation.

"RESOLVED, that the Certificate of Incorporation (as amended) of the Corporation shall be amended by adding at the end of subsection A of Article IV thereof the following: 'Effective upon the effective time of this Certificate of Amendment of the Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Effective Time"), each [intentionally left blank] shares¹ of Common Stock issued and outstanding immediately prior to the Effective Time shall, automatically and without the necessity of any further action, be changed, reclassified and combined into one (1) share of Common Stock (the "Reverse Stock Split"). No fractional shares shall be issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional shares of Common Stock shall have that rounded up to one additional whole share. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional shares as described above.'"

SECOND: That, thereafter, pursuant to the resolution of the Board of Directors, the proposed Amendment was approved by the stockholders of the Corporation at the special meeting of stockholders on , 2023.

THIRD: That the Amendment was duly adopted in accordance with the provisions of Sections 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this Amendment to the Certificate of Incorporation of the Corporation (as amended) to be executed by Robert J. Cobuzzi, Jr., Ph.D., its President and Chief Executive Officer, on this __ day of ____, 2023.

DIFFUSION PHARMACEUTICALS INC.

By: _____
Name: Robert J. Cobuzzi, Jr., Ph.D.
Title: President and Chief Executive Officer

¹ This amendment approves the reverse stock split of the Corporation's common stock, at a ratio in the range of - to -for-one. By approving this amendment, the stockholders of the Corporation would be deemed to approve any ratio within the range referred to above.



Canaccord Genuity LLC
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March 29, 2023

Board of Directors
Diffusion Pharmaceuticals Inc.
300 East Main Street, Suite 201
Charlottesville, VA 22902

Members of the Board:

You have requested our opinion as to the fairness, from a financial point of view, to Diffusion Pharmaceuticals Inc., a Delaware corporation (“Parent”), of the Exchange Ratio pursuant to the Agreement and Plan of Merger proposed to be entered into (the “Merger Agreement”) by and among Parent, Dawn Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Parent (“Merger Sub”), and EIP Pharma, Inc., a Delaware corporation (the “Company”). The Merger Agreement provides for, among other things, the merger of Merger Sub with and into the Company pursuant to which the Company will become a wholly-owned subsidiary of Parent (the “Merger”), and except as otherwise provided in the Merger Agreement, each share of common stock, par value \$0.001 per share, of the Company issued and outstanding immediately prior to the Effective Time of the Merger but after giving effect to the Preferred Stock Conversion and the Note Conversion (excluding any Excluded Shares or any Dissenting Shares) will be converted into the right to receive a number of shares of common stock, par value \$0.001 per share, of Parent (“Parent Common Stock”) equal to the Exchange Ratio. For purposes of this opinion, at your direction and with your consent, we have assumed that the Parent Net Cash will not be less than \$13,500,000 and not more than \$14,500,000, and that the Parent Allocation Percentage will be 0.2275 without adjustment. The terms and conditions of the Merger are more fully set forth in the Merger Agreement. Capitalized terms used but not otherwise defined herein shall have the meanings given to such terms in the Merger Agreement.

Canaccord Genuity LLC (“CG”), as part of its investment banking activities, is regularly engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, secondary distributions of listed and unlisted securities, private placements and valuations for corporate and other purposes. In the ordinary course of business, we and our affiliates may acquire, hold or sell, for our and our affiliates’ own accounts and the accounts of customers, equity, debt and other securities and financial instruments (including bank loans and other obligations) of Parent and the Company, certain of their respective affiliates and any other company that may be involved in the Merger. We have acted as financial advisor to Parent in connection with the Merger. We have received and will receive fees for our services in connection with the Merger, including a portion of which is payable upon rendering this opinion and a significant portion of which is contingent upon the consummation of the Merger. In addition, Parent has agreed to reimburse certain of our expenses and indemnify us for certain liabilities relating to or arising out of our engagement. Other than as related to our current engagement by Parent, we have provided no investment banking or other financial services of a material nature to either Parent or the Company during the two years preceding the date of this opinion for which we received fees. We may provide investment banking and other services to or with respect to Parent, the Company or their respective affiliates in the future, for which we may receive compensation.

In connection with our review of the proposed Merger and developing our opinion, we have, among other things:

- (i) reviewed certain publicly available information relating to Parent and the Company;

- (ii) reviewed certain internal historical financial statements and other historical financial and operating data concerning Parent and the Company provided to us by management of Parent and the Company;
- (iii) reviewed certain projected cash balances of Parent prepared by management of Parent and certain projected financial and operating data of the Company prepared by management of the Company and adjusted by Parent, in each case as provided to us by management of Parent (collectively, the “Projections”);
- (iv) conducted discussions with members of senior management of Parent and the Company regarding the past and current operations and financial condition and the prospects of Parent and the Company;
- (v) reviewed certain financial and stock market data of certain publicly traded companies that we deemed to be relevant to the Company;
- (vi) reviewed certain financial terms of certain initial public offerings executed by certain companies that we deemed to be relevant to the Company;
- (vii) reviewed certain financial terms of certain business combination transactions that we deemed to be relevant to the Merger;
- (viii) reviewed the terms of the Merger Agreement furnished to us by Parent on March 28, 2023, which we have assumed, with your consent, to be identical in all material respects to the agreement to be executed by the parties; and
- (ix) reviewed such other financial studies and analyses, performed such other investigations, and took into account such other matters as we deemed necessary, including an assessment of general securities, economic, market and monetary conditions.

In connection with our review and arriving at our opinion, we have not independently verified any of the foregoing information, have relied on such information, have assumed that all such information is complete and accurate in all material respects, and have relied on assurances of the managements of Parent and the Company that they are not aware of any facts that would make such information misleading in any material respect. With respect to the Projections and other estimated and forward-looking information provided to us by management of Parent and the Company, we have assumed, with your consent, that they have been reasonably prepared on bases reflecting the best currently available estimates and judgments of such management. At your direction, we have used and relied on the Projections for purposes of our analysis and this opinion. We express no view or opinion as to the Projections or the assumptions on which they are based, including, without limitation, any assumptions regarding access to funding for the Company over the projection period. We have also assumed that (i) the Merger will be consummated upon the terms set forth in the Merger Agreement, without waiver, modification or amendment of any material term, condition or agreement therein which would be in any way meaningful to our analysis, (ii) the representations and warranties made by the parties to the Merger Agreement are and will be true and correct in all respects material to our analysis, and (iii) in the course of obtaining necessary governmental, regulatory and third party approvals and consents for the Merger, no modification, delay, limitation, restriction or conditions will be imposed that will have an adverse effect on Parent or the Company or the contemplated benefits of the Merger in any way meaningful to our analysis.

This opinion has been approved by a fairness committee of CG. Our opinion is rendered on the basis of securities, economic, market and monetary conditions prevailing as of the date hereof and on the prospects, financial and otherwise, of Parent and the Company, known to us as of the date hereof. It should be understood that (i) subsequent developments may affect the conclusions expressed in this opinion if this opinion were rendered as of a later date, and (ii) CG disclaims any obligation to advise any person of any change in any manner affecting this opinion that may come to our attention after the date of this opinion. We have not undertaken to reaffirm or revise this opinion or otherwise comment upon any events occurring after the date hereof and do not have any obligation to update, revise or reaffirm this opinion. We have not been requested to conduct and we have not conducted, nor have we relied upon, any independent valuation or appraisal of any of the assets or liabilities of Parent or the Company. We also have not evaluated the solvency of any party to the Merger Agreement under any state, federal or other laws, rules or regulations relating to bankruptcy, insolvency or similar matters. In addition, we have assumed, with your consent, that any material liabilities (contingent or otherwise, known or unknown) of Parent or the Company are as set forth in the financial statements of Parent or the Company provided to us.

This opinion is limited to and addresses only the fairness, from a financial point of view, as of the date hereof, to Parent of the Exchange Ratio pursuant to the Merger Agreement. We do not express any view on, and our opinion does not address, any other term or aspect of any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with the Merger, including, without limitation, any Parent Reverse Split, the Lock-Up Agreements, the Parent Stockholder Support Agreements, the Company Stockholder Support Agreements, or any equity financing by Parent permitted under the Merger Agreement. We also express no opinion as to the fairness of the Merger to the holders of any class of securities, creditors or other constituencies of Parent or the Company. Our opinion does not address the relative merits of the Merger as compared to other business strategies or transactions that might be available to Parent, nor does it address the underlying business decision of Parent to proceed with the Merger or any view on any other term or aspect of the Merger Agreement. We also note that we are not legal, accounting, regulatory or tax experts and have relied on the assessments made by Parent and its advisors with respect to such matters. We have not considered, and we express no opinion as to, the fairness of the amount or nature of the compensation to be paid to any Parent or Company officers, directors or employees, or class of such persons. Further, we express no view or opinion as to in the future what the value of Parent Common Stock actually will be when issued or the price or range of prices at which Parent Common Stock or any other securities may trade or otherwise be transferable at any time, including following announcement or consummation of the Merger.

This opinion, as set forth in this letter form, is solely directed to and for the information of the Board of Directors of Parent (in its capacity as such) in connection with its evaluation of the Merger and does not constitute advice or a recommendation to the Board of Directors as to how the Board of Directors should vote with respect to the Merger Agreement or to any stockholder as to how such stockholder should vote with respect to the Merger or any other aspect of the Merger, or how such stockholders should otherwise act on any matter relating to the Merger. It is understood that this letter may not be disclosed or otherwise referred to without our prior written consent.

Based upon and subject to the foregoing, it is our opinion that, as of the date hereof, the Exchange Ratio pursuant to the Merger Agreement is fair, from a financial point of view, to Parent.

Sincerely,

/s/ Canaccord Genuity LLC

CANACCORD GENUITY LLC

**GENERAL CORPORATION LAW OF THE STATE OF DELAWARE REGARDING
APPRAISAL RIGHTS**

**SECTION 262 OF THE GENERAL CORPORATION LAW OF THE STATE OF
DELAWARE**

§ 262. Appraisal rights

- (a) Any stockholder of a corporation of this State who holds shares of stock on the date of the making of a demand pursuant to subsection (d) of this section with respect to such shares, who continuously holds such shares through the effective date of the merger or consolidation, who has otherwise complied with subsection (d) of this section and who has neither voted in favor of the merger or consolidation nor consented thereto in writing pursuant to § 228 of this title shall be entitled to an appraisal by the Court of Chancery of the fair value of the stockholder's shares of stock under the circumstances described in subsections (b) and (c) of this section. As used in this section, the word "stockholder" means a holder of record of stock in a corporation; the words "stock" and "share" mean and include what is ordinarily meant by those words; and the words "depository receipt" mean a receipt or other instrument issued by a depository representing an interest in one or more shares, or fractions thereof, solely of stock of a corporation, which stock is deposited with the depository.
- (b) Appraisal rights shall be available for the shares of any class or series of stock of a constituent corporation in a merger or consolidation to be effected pursuant to § 251 (other than a merger effected pursuant to § 251(g) of this title), § 252, § 254, § 255, § 256, § 257, § 258, § 263 or § 264 of this title:
- (1) Provided, however, that, except as expressly provided in § 363(b) of this title, no appraisal rights under this section shall be available for the shares of any class or series of stock, which stock, or depository receipts in respect thereof, at the record date fixed to determine the stockholders entitled to receive notice of the meeting of stockholders to act upon the agreement of merger or consolidation (or, in the case of a merger pursuant to § 251(h), as of immediately prior to the execution of the agreement of merger), were either: (i) listed on a national securities exchange or (ii) held of record by more than 2,000 holders; and further provided that no appraisal rights shall be available for any shares of stock of the constituent corporation surviving a merger if the merger did not require for its approval the vote of the stockholders of the surviving corporation as provided in § 251(f) of this title.
- (2) Notwithstanding paragraph (b)(1) of this section, appraisal rights under this section shall be available for the shares of any class or series of stock of a constituent corporation if the holders thereof are required by the terms of an agreement of merger or consolidation pursuant to §§ 251, 252, 254, 255, 256, 257, 258, 263 and 264 of this title to accept for such stock anything except:
- a. Shares of stock of the corporation surviving or resulting from such merger or consolidation, or depository receipts in respect thereof;
 - b. Shares of stock of any other corporation, or depository receipts in respect thereof, which shares of stock (or depository receipts in respect thereof) or depository receipts at the effective date of the merger or consolidation will be either listed on a national securities exchange or held of record by more than 2,000 holders;
 - c. Cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a. and b. of this section; or
 - d. Any combination of the shares of stock, depository receipts and cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a., b. and c. of this section.
- (3) In the event all of the stock of a subsidiary Delaware corporation party to a merger effected under § 253 or § 267 of this title is not owned by the parent immediately prior to the merger, appraisal rights shall be available for the shares of the subsidiary Delaware corporation.

- (4) In the event of an amendment to a corporation's certificate of incorporation contemplated by § 363(a) of this title, appraisal rights shall be available as contemplated by § 363(b) of this title, and the procedures of this section, including those set forth in subsections (d) and (e) of this section, shall apply as nearly as practicable, with the word "amendment" substituted for the words "merger or consolidation," and the word "corporation" substituted for the words "constituent corporation" and/or "surviving or resulting corporation."
- (c) Any corporation may provide in its certificate of incorporation that appraisal rights under this section shall be available for the shares of any class or series of its stock as a result of an amendment to its certificate of incorporation, any merger or consolidation in which the corporation is a constituent corporation or the sale of all or substantially all of the assets of the corporation. If the certificate of incorporation contains such a provision, the provisions of this section, including those set forth in subsections (d), (e), and (g) of this section, shall apply as nearly as is practicable.
- (d) Appraisal rights shall be perfected as follows:
- (1) If a proposed merger or consolidation for which appraisal rights are provided under this section is to be submitted for approval at a meeting of stockholders, the corporation, not less than 20 days prior to the meeting, shall notify each of its stockholders who was such on the record date for notice of such meeting (or such members who received notice in accordance with § 255(c) of this title) with respect to shares for which appraisal rights are available pursuant to subsection (b) or (c) of this section that appraisal rights are available for any or all of the shares of the constituent corporations, and shall include in such notice a copy of this section and, if one of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Each stockholder electing to demand the appraisal of such stockholder's shares shall deliver to the corporation, before the taking of the vote on the merger or consolidation, a written demand for appraisal of such stockholder's shares; provided that a demand may be delivered to the corporation by electronic transmission if directed to an information processing system (if any) expressly designated for that purpose in such notice. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such stockholder's shares. A proxy or vote against the merger or consolidation shall not constitute such a demand. A stockholder electing to take such action must do so by a separate written demand as herein provided. Within 10 days after the effective date of such merger or consolidation, the surviving or resulting corporation shall notify each stockholder of each constituent corporation who has complied with this subsection and has not voted in favor of or consented to the merger or consolidation of the date that the merger or consolidation has become effective; or
- (2) If the merger or consolidation was approved pursuant to § 228, § 251(h), § 253, or § 267 of this title, then either a constituent corporation before the effective date of the merger or consolidation or the surviving or resulting corporation within 10 days thereafter shall notify each of the holders of any class or series of stock of such constituent corporation who are entitled to appraisal rights of the approval of the merger or consolidation and that appraisal rights are available for any or all shares of such class or series of stock of such constituent corporation, and shall include in such notice a copy of this section and, if 1 of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Such notice may, and, if given on or after the effective date of the merger or consolidation, shall, also notify such stockholders of the effective date of the merger or consolidation. Any stockholder entitled to appraisal rights may, within 20 days after the date of giving such notice or, in the case of a merger approved pursuant to § 251(h) of this title, within the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days after the date of giving such notice, demand in writing from the surviving or resulting corporation the appraisal of such holder's shares; provided that a demand may be delivered to the corporation by electronic transmission if directed to an information processing system (if any) expressly designated for that purpose in such notice. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such holder's shares. If such notice did not notify stockholders of the effective date of the merger or consolidation, either (i) each such constituent corporation shall send a second notice before the effective date of the merger or consolidation notifying each of the holders of any class or series of stock of such constituent corporation that are entitled to appraisal rights of the effective date of the merger or consolidation or (ii) the surviving or resulting corporation shall send such a second notice to all such holders on or within 10 days after such effective date; provided, however, that if such second notice is sent more than 20 days following the sending of the first notice or, in the case of a merger approved pursuant to § 251(h) of this title, later than the later of the consummation of the offer contemplated by § 251(h) of this title and 20 days following the sending of the first notice, such second notice need only be sent to each stockholder who is entitled to appraisal rights and who has demanded appraisal of such holder's shares in accordance with this subsection. An affidavit of the secretary or assistant secretary or of the transfer agent of the corporation that is required to give either notice that such notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein. For purposes of determining the stockholders entitled to receive either notice, each constituent corporation may fix, in advance, a record date that shall be not more than 10 days prior to the date the notice is given, provided, that if the notice is given on or after the effective date of the merger or consolidation, the record date shall be such effective date. If no record date is fixed and the notice is given prior to the effective date, the record date shall be the close of business on the day next preceding the day on which the notice is given.

- (e) Within 120 days after the effective date of the merger or consolidation, the surviving or resulting corporation or any stockholder who has complied with subsections (a) and (d) of this section hereof and who is otherwise entitled to appraisal rights, may commence an appraisal proceeding by filing a petition in the Court of Chancery demanding a determination of the value of the stock of all such stockholders. Notwithstanding the foregoing, at any time within 60 days after the effective date of the merger or consolidation, any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party shall have the right to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation. Within 120 days after the effective date of the merger or consolidation, any stockholder who has complied with the requirements of subsections (a) and (d) of this section hereof, upon request given in writing (or by electronic transmission directed to an information processing system (if any) expressly designated for that purpose in the notice of appraisal), shall be entitled to receive from the corporation surviving the merger or resulting from the consolidation a statement setting forth the aggregate number of shares not voted in favor of the merger or consolidation (or, in the case of a merger approved pursuant to § 251(h) of this title, the aggregate number of shares (other than any excluded stock (as defined in § 251(h)(6)d. of this title)) that were the subject of, and were not tendered into, and accepted for purchase or exchange in, the offer referred to in § 251(h)(2)), and, in either case, with respect to which demands for appraisal have been received and the aggregate number of holders of such shares. Such statement shall be given to the stockholder within 10 days after such stockholder's request for such a statement is received by the surviving or resulting corporation or within 10 days after expiration of the period for delivery of demands for appraisal under subsection (d) of this section hereof, whichever is later. Notwithstanding subsection (a) of this section, a person who is the beneficial owner of shares of such stock held either in a voting trust or by a nominee on behalf of such person may, in such person's own name, file a petition or request from the corporation the statement described in this subsection.
- (f) Upon the filing of any such petition by a stockholder, service of a copy thereof shall be made upon the surviving or resulting corporation, which shall within 20 days after such service file in the office of the Register in Chancery in which the petition was filed a duly verified list containing the names and addresses of all stockholders who have demanded payment for their shares and with whom agreements as to the value of their shares have not been reached by the surviving or resulting corporation. If the petition shall be filed by the surviving or resulting corporation, the petition shall be accompanied by such a duly verified list. The Register in Chancery, if so ordered by the Court, shall give notice of the time and place fixed for the hearing of such petition by registered or certified mail to the surviving or resulting corporation and to the stockholders shown on the list at the addresses therein stated. Such notice shall also be given by one or more publications at least one week before the day of the hearing, in a newspaper of general circulation published in the City of Wilmington, Delaware or such publication as the Court deems advisable. The forms of the notices by mail and by publication shall be approved by the Court, and the costs thereof shall be borne by the surviving or resulting corporation.
- (g) At the hearing on such petition, the Court shall determine the stockholders who have complied with this section and who have become entitled to appraisal rights. The Court may require the stockholders who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with such direction, the Court may dismiss the proceedings as to such stockholder. If immediately before the merger or consolidation the shares of the class or series of stock of the constituent corporation as to which appraisal rights are available were listed on a national securities exchange, the Court shall dismiss the proceedings as to all holders of such shares who are otherwise entitled to appraisal rights unless (1) the total number of shares entitled to appraisal exceeds 1% of the outstanding shares of the class or series eligible for appraisal, (2) the value of the consideration provided in the merger or consolidation for such total number of shares exceeds \$1 million, or (3) the merger was approved pursuant to § 253 or § 267 of this title.

- (h) After the Court determines the stockholders entitled to an appraisal, the appraisal proceeding shall be conducted in accordance with the rules of the Court of Chancery, including any rules specifically governing appraisal proceedings. Through such proceeding the Court shall determine the fair value of the shares exclusive of any element of value arising from the accomplishment or expectation of the merger or consolidation, together with interest, if any, to be paid upon the amount determined to be the fair value. In determining such fair value, the Court shall take into account all relevant factors. Unless the Court in its discretion determines otherwise for good cause shown, and except as provided in this subsection, interest from the effective date of the merger through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5% over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective date of the merger and the date of payment of the judgment. At any time before the entry of judgment in the proceedings, the surviving corporation may pay to each stockholder entitled to appraisal an amount in cash, in which case interest shall accrue thereafter as provided herein only upon the sum of (1) the difference, if any, between the amount so paid and the fair value of the shares as determined by the Court, and (2) interest theretofore accrued, unless paid at that time. Upon application by the surviving or resulting corporation or by any stockholder entitled to participate in the appraisal proceeding, the Court may, in its discretion, proceed to trial upon the appraisal prior to the final determination of the stockholders entitled to an appraisal. Any stockholder whose name appears on the list filed by the surviving or resulting corporation pursuant to subsection (f) of this section and who has submitted such stockholder's certificates of stock to the Register in Chancery, if such is required, may participate fully in all proceedings until it is finally determined that such stockholder is not entitled to appraisal rights under this section.
- (i) The Court shall direct the payment of the fair value of the shares, together with interest, if any, by the surviving or resulting corporation to the stockholders entitled thereto. Payment shall be so made to each such stockholder, in the case of holders of uncertificated stock forthwith, and the case of holders of shares represented by certificates upon the surrender to the corporation of the certificates representing such stock. The Court's decree may be enforced as other decrees in the Court of Chancery may be enforced, whether such surviving or resulting corporation be a corporation of this State or of any state.
- (j) The costs of the proceeding may be determined by the Court and taxed upon the parties as the Court deems equitable in the circumstances. Upon application of a stockholder, the Court may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorney's fees and the fees and expenses of experts, to be charged pro rata against the value of all the shares entitled to an appraisal.
- (k) From and after the effective date of the merger or consolidation, no stockholder who has demanded appraisal rights as provided in subsection (d) of this section shall be entitled to vote such stock for any purpose or to receive payment of dividends or other distributions on the stock (except dividends or other distributions payable to stockholders of record at a date which is prior to the effective date of the merger or consolidation); provided, however, that if no petition for an appraisal shall be filed within the time provided in subsection (e) of this section, or if such stockholder shall deliver to the surviving or resulting corporation a written withdrawal of such stockholder's demand for an appraisal and an acceptance of the merger or consolidation, either within 60 days after the effective date of the merger or consolidation as provided in subsection (e) of this section or thereafter with the written approval of the corporation, then the right of such stockholder to an appraisal shall cease. Notwithstanding the foregoing, no appraisal proceeding in the Court of Chancery shall be dismissed as to any stockholder without the approval of the Court, and such approval may be conditioned upon such terms as the Court deems just; provided, however that this provision shall not affect the right of any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation within 60 days after the effective date of the merger or consolidation, as set forth in subsection (e) of this section.
- (l) The shares of the surviving or resulting corporation to which the shares of such objecting stockholders would have been converted had they assented to the merger or consolidation shall have the status of authorized and unissued shares of the surviving or resulting corporation.

PART II

**INFORMATION NOT REQUIRED IN
PROXY STATEMENT/PROSPECTUS/INFORMATION STATEMENT**

Item 20. *Indemnification of Directors and Officers*

As permitted by Section 102 of the DGCL, Diffusion's certificate of incorporation eliminates the liability of directors to Diffusion or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent otherwise required by the DGCL, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

Section 145 of the DGCL permits indemnification of officers and directors under certain circumstances in connection with liabilities (including reimbursement for expenses incurred) arising under the Securities Act. The certificate of incorporation provides that Diffusion will indemnify any person who is or was made a party to any proceeding by reason of the fact that such person is or was a director or officer of Diffusion against expenses, judgments, fines, penalties, and amounts paid in settlement incurred in connection therewith to the fullest extent authorized by the DGCL. Diffusion's bylaws provide for a similar indemnity to directors and officers of Diffusion to the fullest extent authorized by the DGCL.

Diffusion's bylaws authorize Diffusion's board of directors to enter into indemnification contracts with each of its officers and directors. Diffusion has entered into indemnification contracts with each of its directors and executive officers. The indemnification contracts provide for the indemnification of directors and officers against all expenses, liability, and loss actually reasonably incurred to the fullest extent permitted by Diffusion's certificate of incorporation, bylaws, and applicable law.

Diffusion's bylaws also authorize Diffusion to maintain insurance to protect any director or officer against any expense, liability, or loss, whether or not Diffusion would have the power to indemnify such person against such expense, liability, or loss under the DGCL.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of Diffusion pursuant to the foregoing provisions, Diffusion has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Item 21. *Exhibits and Financial Statement Schedules*

(a) Exhibit Index

A list of exhibits filed with this registration statement on Form S-4 is set forth on the Exhibit Index and is incorporated herein by reference.

INDEX TO EXHIBITS

Exhibit No.	Description
2.1Δ	Agreement and Plan of Merger, dated as of March 30, 2023, by and among Diffusion Pharmaceuticals Inc., EIP Pharma, Inc. and Dawn Merger Sub Inc. (Incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K filed on March 30, 2023)
3.1	Certificate of Incorporation of Diffusion Pharmaceuticals Inc., as amended (Incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 24, 2023)
3.2	Bylaws of Diffusion Pharmaceuticals Inc., as amended (Incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 24, 2023)
3.3	Certificate of Designation of Preferences, Rights, and Limitations of Series C Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on March 18, 2022)
4.1	Form of 2018 Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed on January 19, 2018)
4.2	Form of 2018 Underwriter's Warrant (Incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on January 22, 2018)
4.3	Form of May 2019 Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed on May 28, 2019)
4.4	Form of May 2019 Placement Agent's Warrant (Incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on May 28, 2019)
4.5	Form of November 2019 Series I Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed on November 13, 2019)
4.6	Form of November 2019 Series II Common Stock Warrant (Incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on November 13, 2019)
4.7	Form of December 2019 Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed on December 13, 2019)
4.8	Form of December 2019 Placement Agent's Warrant (Incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on December 13, 2019)
4.9	Form of May 2020 Placement Agent's Warrant (In Respect of Exercise Transaction) (Incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on May 8, 2020)
4.10	Form of May 2020 Placement Agent's Warrant (In Respect of Offering Transaction) (Incorporated by reference to Exhibit 4.3 to the registrant's Current Report on Form 8-K filed on May 20, 2020)
4.11	Form of February 2021 Underwriter's Warrant (Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed on February 18, 2021)
5.1**	Opinion of Dechert LLP
8.1**	Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. regarding tax matters
10.1#	Employment Agreement dated as of September 8, 2020 by and between Robert J. Cobuzzi, Jr., Ph.D. and Diffusion Pharmaceuticals Inc. (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed on September 9, 2020)
10.2#	Amended and Restated Employment Agreement, dated as of September 21, 2018, by and between William Karl Hornung and Diffusion Pharmaceuticals Inc. (Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed September 27, 2018)
10.3#	Employment Agreement, dated as of October 19, 2020, by and between Christopher D. Galloway, M.D. and Diffusion Pharmaceuticals Inc. (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed October 20, 2020)
10.4#	Employment Agreement, dated as of September 23, 2020, by and between William Elder and Diffusion Pharmaceuticals Inc. (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed September 25, 2020)
10.5#	Employment Agreement, effective as of May 18, 2022, by and between Raven Jaeger and Diffusion Pharmaceuticals Inc. (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed June 28, 2022)
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- 10.6# [Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan \(Incorporated by reference to Appendix C to the registrant's definitive proxy statement on Schedule 14A filed on June 10, 2016\)](#)
- 10.7# [Amendment No. 1 to Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan \(Incorporated by reference to Appendix B to the registrant's definitive proxy statement on Schedule 14A filed on June 10, 2016\)](#)
- 10.8# [Form of Stock Option Award Agreement under 2015 Equity Incentive Plan \(Incorporated by reference to Exhibit 10.7 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021\)](#)
- 10.9# [Form of Director RSU Agreement under 2015 Equity Incentive Plan \(Incorporated by reference to Exhibit 10.8 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2021\)](#)
- 10.10# [Form of Diffusion Pharmaceuticals LLC Stock Option Award Agreement \(Incorporated by reference to Exhibit 10.24 to the registrant's annual report on Form 10-K for the year ended December 31, 2015\)](#)
- 10.11# [Form of Indemnification Agreement between Diffusion Pharmaceuticals Inc. and each of its Directors and Officers \(Incorporated by reference to Exhibit 10.3 to the registrant's annual report on Form 10-K for the year ended December 31, 2015\)](#)
- 10.12 [Form of Subscription Agreement between Diffusion Pharmaceuticals Inc. and the investors named there, dated March 18, 2022 \(Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed March 18, 2022\)](#)
- 10.13 [Settlement Agreement, dated as of December 15, 2022, by and among Diffusion Pharmaceuticals Inc, LifeSci Special Opportunities Master Fund Ltd., LifeSci Special Opportunities Partners L.P., LifeSci Special Opportunities Offshore Fund, Ltd., LifeSci Special Opportunities Partners GP, LLC, LifeSci Management Company LLC, Pirate Cove Capital Ltd. and David Dobkin \(Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed December 16, 2022\)](#)
- 10.14 [Separation Agreement and General Release, effective as of March 8, 2023, by and between Diffusion Pharmaceuticals and Christopher D. Galloway, M.D. \(Incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 24, 2023\)](#)
- 10.15 [Separation Agreement and General Release, effective as of March 8, 2023, by and between Diffusion Pharmaceuticals and Raven Jaeger \(Incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 24, 2023\)](#)
- 10.16 [At-The-Market Sales Agreement, dated as of July 22, 2022, by and between Diffusion Pharmaceuticals Inc. and BTIG, LLC \(Incorporated by reference to Exhibit 1.1 to the registrant's Current Report on Form 8-K filed on July 22, 2022\)](#)
- 10.17 [Form of EIP Pharma, Inc. Stockholder Support Agreement, dated as of March 30, 2023 \(Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on March 30, 2023\)](#)
- 10.18 [Form of Diffusion Pharmaceuticals Inc. Stockholder Support Agreement, dated as of March 30, 2023 \(Incorporated by reference to Exhibit 99.1 to the registrant's Current Report on Form 8-K filed on March 30, 2023\)](#)
- 10.19 [Form of Lock-up Agreement, dated as of March 30, 2023 \(Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed on March 30, 2023\)](#)
- 10.20# [Amendment, dated March 29, 2023, to Employment Agreement, dated September 8, 2020, by and between Diffusion Pharmaceuticals Inc. and Robert J. Cobuzzi, Ph.D. \(Incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed on March 30, 2023\)](#)
- 10.21# [Amendment, dated March 29, 2023, to Employment Agreement, dated September 21, 2018, by and between Diffusion Pharmaceuticals Inc. and William Hornung \(Incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed on March 30, 2023\)](#)
- 10.22# [Amendment, dated March 29, 2023, to Employment Agreement, dated September 23, 2020, by and between Diffusion Pharmaceuticals Inc. and William Elder \(Incorporated by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed on March 30, 2023\)](#)

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10.23Δ Δ*	Option and License Agreement, dated as of August 27, 2012, by and between EIP Pharma LLC and Vertex Pharmaceuticals Incorporated
10.24Δ Δ*	Amendment No.1, dated as of April 8, 2014, to Option and License Agreement, dated August 27, 2012, by and between EIP Pharma LLC and Vertex Pharmaceuticals Incorporated
10.25Δ Δ*	Amendment No.2, dated as of November 17, 2015, to Option and License Agreement, dated August 27, 2012, as amended April 18, 2014, by and between EIP Pharma LLC and Vertex Pharmaceuticals Incorporated
10.26##*	Executive Employment Agreement, dated as of April 2, 2018, by and between EIP Pharma, Inc., and Sylvie Gregoire
10.27##*	Amendment No. 1, dated as of March 4, 2019, to Executive Employment Agreement, dated as of April 2, 2018, by and between EIP Pharma, Inc., and Sylvie Gregoire
10.28##*	Executive Employment Agreement, effective as of April 2, 2018, by and between EIP Pharma, Inc., and John Alam, M.D.
10.29##*	Offer Letter, dated as of April 29, 2018, by and between EIP Pharma, Inc., and Kelly Blackburn
10.30##*	Amendment, dated as of January 29, 2019, to Offer Letter, dated April 29, 2018, by and between EIP Pharma, Inc., and Kelly Blackburn
10.31##*	2018 Employee, Director and Consultant Equity Incentive Plan, effective as of March 28, 2019
21.1	Subsidiaries of Diffusion Pharmaceuticals Inc. (Incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 24, 2023)
23.1*	Consent of KPMG LLP, independent registered public accounting firm
23.2*	Consent of RSM US LLP, independent registered public accounting firm
23.3**	Consent of Dechert LLP (Included in Exhibit 5.1)
23.4**	Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (Included in Exhibit 8.1)
24.1*	Power of Attorney (included on the signature page of this Registration Statement on Form S-4)
99.1*	Director Consent (John Alam, M.D.)
99.2*	Director Consent (Sylvie Grégoire, PharmD.)
99.3*	Director Consent (Jeff Poulton)
99.4*	Director Consent (Marwan Sabbagh, M.D.)
99.5*	Director Consent (Frank Zavrl)
99.6**	Proposed Amendment to Amended and Restated Certificate of the Registrant (included as Annex B to the proxy statement/prospectus/information statement forming a part of this Registration Statement)
99.7**	Form of Proxy Card for Special Meeting of Diffusion Pharmaceuticals Inc.
99.8*	Consent of Canaccord Genuity LLC, financial advisor to Diffusion
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)
107*	Filing Fee Table

* Filed herewith.

** To be filed by amendment.

Δ Schedules and exhibits have been omitted from this filing pursuant to Item 601(a)(5) of Regulation S-K. Diffusion agrees to furnish on a supplemental basis a copy of any omitted schedule or exhibit to the SEC upon its request; provided, however, that Diffusion may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule or exhibit so furnished.

Δ Δ Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

Indicates a management contract or compensatory plan or arrangement.

(b) Financial Statements

The financial statements filed with this registration statement on Form S-4 are set forth on the Financial Statement Index and are incorporated herein by reference.

Item 22. Undertakings

(a) The undersigned registrant hereby undertakes as follows:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by section 10(a)(3) of the Securities Act;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes as follows:

- (1) That, prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the issuer undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.
- (2) That, every prospectus (i) that is filed pursuant to paragraph (b)(1) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

- (c) The undersigned registrant hereby undertakes that, insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (d) The undersigned registrant hereby undertakes to respond to requests for information that is incorporated by reference into the prospectus pursuant to Item 4, 10(b), 11, or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.
- (e) The undersigned registrant hereby undertakes to supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Charlottesville, State of Virginia, on May 10, 2023.

DIFFUSION PHARMACEUTICALS INC.

By: /s/ Robert J. Cobuzzi, Jr., Ph.D.
Robert J. Cobuzzi, Jr., Ph.D.
President, Chief Executive Officer, and Director
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert J. Cobuzzi, Jr., Ph.D and William Elder as his or her true and lawful attorney-in-fact and agent, with full powers of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments and any related registration statements filed pursuant to Rule 462 and otherwise), and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent and full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or resubstitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name and Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Robert J. Cobuzzi, Jr., Ph.D.</u> Robert J. Cobuzzi, Jr., Ph.D.	President, Chief Executive Officer, and Director (Principal Executive Officer)	May 10, 2023
<u>/s/ William K. Hornung</u> William K. Hornung	Chief Financial Officer (Principal Financial and Accounting Officer)	May 10, 2023
<u>/s/ Jane H. Hollingsworth</u> Jane H. Hollingsworth	Chair of the Board	May 10, 2023
<u>/s/ Robert Adams</u> Robert Adams	Director	May 10, 2023
<u>/s/ Mark T. Giles</u> Mark T. Giles	Director	May 10, 2023
<u>/s/ Diana Lanchoney</u> Diana Lanchoney	Director	May 10, 2023
<u>/s/ Alan Levin</u> Alan Levin	Director	May 10, 2023

OPTION AND LICENSE AGREEMENT

BY AND BETWEEN

EIP PHARMA LLC

AND

VERTEX PHARMACEUTICALS INCORPORATED

*****] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

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[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

OPTION AND LICENSE AGREEMENT

This Option and License Agreement (this "Agreement"), made this 27th day of August, 2012 (the "Effective Date"), is by and between DP Pharma LLC, a Massachusetts limited liability company, with principal offices located at 11 Channing Street, Cambridge, MA 02138 ("EIP") and Vertex Pharmaceuticals Incorporated, a Delaware corporation, with principal offices located at 130 Waverly Street, Cambridge, MA 02139 ("Vertex"). Each of EIP and Vertex may be referred to, individually, as a "Party", and, collectively, as the "Parties".

RECITALS

WHEREAS, Vertex owns certain patent rights and know-how related to a small molecule p38 MAP kinase inhibitor known as VX-745;

WHEREAS, Vertex and EIP are parties to a Material Transfer Agreement dated September 7, 2010 (the "MTA") pursuant to which Vertex provided EIP a specific quantity of VX-745 to allow EIP to perform certain investigational, pre-clinical studies;

WHEREAS, EIP is interested in obtaining an option to acquire an exclusive license to develop and commercialize VX-745, and Vertex is willing to grant EIP such an option, in each case on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained in this Agreement, Vertex and EIP, intending to be legally bound, hereby agree as follows:

ARTICLE I DEFINITIONS

When used in this Agreement, each of the following capitalized terms, whether used in the singular or plural, shall have the meanings set forth in this Article 1.

1.1 "Affiliate" of an entity means any person or entity which, directly or indirectly, controls, is controlled by or is under common control with such entity. For the purposes of this definition, "control" refers to any of the following: (i) direct or indirect ownership of fifty percent (50%) or more of the voting securities entitled to vote for the election of directors in the case of a corporation, or of fifty percent (50%) or more of the equity interest with the power to direct management in the case of any other type of legal entity; (ii) status as a general partner in any partnership; or (iii) any other arrangement where a person or entity possesses, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract or otherwise.

1.2 "Analogs" means those specific analogs to VX-745 that are selected by EIP as back-up compounds in accordance with the process, and subject to the limitations, set forth in Section 2.8.

1.3 “Combination Product” means any pharmaceutical product containing both a Licensed Product component and one or more other active pharmaceutical ingredients or other significant components.

1.4 “Commencement” or “Commence” means, with respect to a clinical trial, dosing of the first person in the clinical trial.

1.5 “Commercial Plan” means the written plan describing the activities to be carried out by EIP for commercialization of Licensed Product, which shall include a budget and estimate of the number of FTEs to be expended during the period covered thereby in key commercial areas including sales, medical affairs, and patient safety.

1.6 “Commercially Reasonable Efforts” means the level of efforts and resources (measured as of the time that such efforts are required to be exerted pursuant to this Agreement) commonly used by a company of a similar size to that of the Party required to exert the specified level of effort to conduct the relevant activity, including, in the case of research, development or commercialization, the level of effort and resources used by such a company to research, develop, manufacture or commercialize, as the case may be, a product owned by such company or to which it has rights, which product is at a similar stage in its development or product life and is of a similar market potential to Licensed Product, taking into account all relevant factors including the patent and other proprietary position of the product, product labeling or anticipated labeling, market potential, financial return, medical and clinical considerations, regulatory environments and competitive market conditions, and other technical, legal, scientific, medical or commercial factors that such a company would deem to be relevant.

1.7 “Completion” means, with respect to a clinical trial, delivery to Vertex of a report setting forth in reasonable detail data and customary statistical analysis of such data such that the reader has sufficient information to understand the outcome of the clinical trial.

1.8 “Confidential Information” means any and all information, data and materials of a confidential or proprietary nature, which are provided by or on behalf of one Party or any of its Affiliates to the other Party or any of its Affiliates in connection with this Agreement.

1.9 “Control” or “Controlled”, other than for purposes of Section 1.1, means the possession of the right to grant licenses or sublicenses or to disclose proprietary or trade secret information without violating the terms of any agreement or other arrangement with a Third Party and without misappropriating or infringing the proprietary or trade secret information of a Third Party.

1.10 “Cover”, “Covering” or “Covered” means, with respect to a Patent Right and invention, that, in the absence of ownership of, or a license under, such Patent Right, the practice of such invention would infringe a Valid Claim of such Patent Right (including in the case of a Patent Right that is a patent application, a Valid Claim of such patent application as if such patent application were an issued patent).

1.11 “Development Plan” means the written plan describing the activities to be carried out by EIP for development of Licensed Product leading to Marketing Approval, which shall include all clinical trial designs as well as CMC and all other non-clinical activities, objectives for achievement of the Minimum Diligence Requirements, budget, and estimate of the number of FTEs to be expended during the period covered thereby.

1.12 “EIP Background Patent Rights” means any Patent Rights owned or Controlled by EIP that Cover Licensed Product, excluding (i) EIP Product Patent Rights and (ii) any Patent Rights licensed to EIP under this Agreement.

1.13 “EIP Product Know-how” means any Know-how Controlled, generated, conceived or reduced to practice by or on behalf of EIP or any of its Affiliates during the term of the MTA and the Term that (i) has been incorporated into Licensed Product or the manufacturing process for Licensed Product during the Term (ii) constitutes a new use of Licensed Product or (iii) is otherwise necessary for the further development, manufacture, commercialization or use of Licensed Product.

1.14 “EIP Product Patent Rights” means any Patent Rights owned or otherwise Controlled by EIP or any of its Affiliates Covering EIP Product Know-how.

1.15 “EIP Product Technology” means, collectively, EIP Product Know-how and EIP Product Patent Rights.

1.16 “EMA” means the European Medicines Agency or any successor agency.

1.17 “EU” means the countries of the European Union, as it is constituted as of the Effective Date and as it may be expanded from time to time.

1.18 “FDA” means the United States Food and Drug Administration or any successor agency thereto.

1.19 “FDA Meeting” means a meeting between EIP or any of its Affiliates and the FDA for the purpose of discussing, and gaining FDA’s agreement on, the size, design and endpoints of a Phase 2 Clinical Trial of Licensed Product.

1.20 “Field” means the diagnosis, treatment, and prevention of Alzheimer’s disease and related central nervous system disorders in humans.

1.21 “First Commercial Sale”, as to a particular country, means the first commercial sale of a Licensed Product by EIP or any of its Affiliates or Sublicensees to a Third Party in an arm’s length transaction in such country after approval of the NDA, or if approval of an NDA is not required in such country, then following receipt of Marketing Approval required to market such Licensed Product in such country.

1.22 “FTE” means a full-time equivalent person year of one thousand eight hundred eighty (1,880) hours per year, with any portion of an FTE calculated based upon hours worked divided by such annual total.

1.23 “IND” means an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application (CTA) or a clinical trial exemption (CTX).

1.24 “Know-how” means all biological materials and other tangible materials, inventions, practices, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, procedures, assays, skills, experience, techniques, data and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical test data and analytical and quality control data, patentable or otherwise.

1.25 “Licensed Product” means any product comprising, incorporating or containing VX-745 or any Analog, or an alternate form of VX-745 or any Analog, including, but not limited to, a pharmaceutically acceptable salt, polymorph, crystal form, prodrug, or solvate of VX-745 or an Analog.

1.26 “License Term” means the period commencing upon the Option Exercise Date and ending upon expiration or earlier termination of this Agreement pursuant to Article IX.

1.27 “Major Markets” means the United States, France, Germany, Italy, Spain, the United Kingdom, Japan, India, Brazil, Russia, and China, subject to adjustment as set forth in Section 9.3(b).

1.28 “Marketing Approval” means any approval, including registration, license or authorization from any Regulatory Authority required to market and sell a Licensed Product in such jurisdiction and shall include an approval, registration, license or authorization granted in connection with an NDA.

1.29 “Net Sales” means the gross amount invoiced on sales of Licensed Product in the Territory by EIP, its Affiliates or Sublicensees to any Third Party in the Field, less the following deductions with respect to the sale of such Licensed Product:

- (i) normal trade, cash and quantity discounts and other customary discounts actually given to customers in the ordinary course of business;
- (ii) rebates, credits and allowances given by reason of rejections, returns, damaged or defective product or recalls;
- (iii) government-mandated rebates and any other compulsory payments, credits, adjustments and rebates actually paid or deducted;

(iv) price adjustments, allowances, credits, chargeback payments, discounts, rebates, fees, reimbursements or similar payments granted to managed care organizations, group purchasing organizations or other buying groups, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other health care institutions (including hospitals), Third Party health care administrators or patient assistance or other similar programs, or to federal, state/provincial, local and other governments, including their agencies, or to wholesalers, distributors or other trade customers;

(v) reasonable and customary freight, shipping, insurance and other transportation expenses, if actually borne by such EIP or its Affiliates or Sublicensees without reimbursement from any Third Party;

(vi) reasonable distribution commissions and fees payable to Third Party wholesalers for distribution of Licensed Product;

(vii) sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, delivery or use of Licensed Product (but not including taxes assessed directly against the income derived from such sale); and

(viii) amounts previously included in Net Sales of Licensed Product that are written off as uncollectible in accordance with standard practices of the applicable party.

Notwithstanding anything in this Agreement to the contrary, the transfer of a Licensed Product between or among EIP, its Affiliates and Sublicensees will not be considered a sale.

Net Sales will include the cash consideration received on a sale and the fair market value of all non-cash consideration. In the event Licensed Product is sold other than in an arm's length transaction, Net Sales for such sale will be determined using the average per unit Net Sales amount for the preceding calendar quarter.

Disposal of Licensed Product for, or use of the Licensed Product in, clinical trials or other scientific testing, as free samples, or under compassionate use or patient assistance or other similar programs or studies where a Licensed Product is supplied without charge shall not result in any Net Sales, however if EIP or its Affiliates or Sublicensees charges for such Licensed Product, the amount billed will be included in the calculation of Net Sales.

Net Sales will be determined on an accrual basis from books and records maintained in accordance with accounting principles generally accepted in the United States, consistently applied throughout the organization and across all products of the entity whose sales of Licensed Product are giving rise to Net Sales.

In the event a Licensed Product is sold in the form of a Combination Product, then the Net Sales for any such Combination Product shall be determined by multiplying the Net Sales of the Combination Product during the applicable royalty reporting period, by the fraction, $A/(A+B)$, where A is the weighted (by sales volume) average sale price of the Licensed Product component when sold separately in finished form in the country in which the Combination Product is sold and B is the weighted (by sales volume) average sale price of the other active pharmaceutical ingredients or significant components included in the Combination Product when sold separately in finished form in the country in which the Combination Product is sold, in each case during the applicable royalty reporting period or, if sales of both the Licensed Product component and the other active pharmaceutical ingredients or significant components did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other active pharmaceutical ingredients or significant components included in the Combination Product, then the Parties will in good faith discuss and agree on a pro-rata allocation of the Net Sales that reflects the Licensed Product's contribution to the Combination Product on an equitable basis.

1.30 "NDA" means a New Drug Application, Biologics License Application or equivalent submission filed with the FDA in connection with seeking Marketing Approval of a Licensed Product, or an equivalent application filed with any equivalent regulatory agency or governmental authority in any jurisdiction other than the United States.

1.31 "Option" has the meaning set forth in Section 2.1.

1.32 "Option Exercise Date" has the meaning set forth in Section 2.3.

1.33 "Option Exercise Fee" has the meaning set forth in Section 4.1.

1.34 "Option Exercise Notice" has the meaning set forth in Section 2.3.

1.35 "Option Period" has the meaning set forth in Section 2.2.

1.36 "Patent Rights" means patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, and extensions and the like thereof, and all counterparts thereof in any country.

1.37 "Phase 2 Clinical Trial" means a human clinical trial, for which the primary endpoints include a determination of dose ranges or an indication of efficacy in patients being studied as described in 21 C.F.R. §312.21(b), or an equivalent clinical trial in a country in the Territory other than the United States.

1.38 "Phase 2b Clinical Trial" means a Phase 2 Clinical Trial designed to generate a substantive indication of efficacy.

1.39 “Phase 3 Clinical Trial” means a human clinical trial that is prospectively designed to demonstrate statistically whether a product is safe and effective for use in humans in the indication being investigated in a manner sufficient to obtain Marketing Approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. §312.21(c), or an equivalent clinical trial in a country in the Territory other than the United States.

1.40 “Research Plan” has the meaning set forth in Section 2.4.

1.41 “Regulatory Authority” means any federal, national, multinational, state, county, city, provincial, or local regulatory agency, department, bureau or other governmental entity with authority over the marketing, commercialization, manufacture or sale of a pharmaceutical product in the Territory, including the FDA in the United States and the EMA in the EU.

1.42 “Royalty Term” has the meaning set forth in Section 4.4.

1.43 “Sublicensee” means a Third Party to whom EIP or any of its Affiliates or another Sublicensee grants an express sublicense under the Vertex Patent Rights or Vertex Know-how to develop, manufacture, commercialize or use Licensed Product in the Field, but does not include any wholesaler or third party distributor who re-sells a Licensed Product purchased from EIP or any of its Affiliates or Sublicensees in final finished form (but not necessarily in final packaged, and labeled form), provided that Vertex is paid the royalty specified in Section 4.3 on the purchase price of such Licensed Product paid by such wholesaler or distributor to Elf’ or any of its Affiliates or Sublicensees.

1.44 “Technology Transfer Plan” means the plan for transfer to EIP of Vertex Know-how attached to this Agreement as Exhibit A.

1.45 “Term” means the term of this Agreement determined in accordance with Section 9.1.

1.46 “Territory” means worldwide, subject to adjustment as set forth in Section 9.3(b).

1.47 “Third Party” means any Person other than a Party or any of its Affiliates or their respective employees.

1.48 “United States” or “U.S.” means the United States of America and its territories and possessions.

1.49 “Valid Claim” means (i) a claim of an issued and unexpired patent that has not been held disclaimed, revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or been dedicated to the public, and (ii) a claim in a pending patent application that is being prosecuted and that has not been abandoned, disclaimed, allowed to lapse or finally determined to be unallowable by the applicable governmental authority in a decision from which no appeal can be taken or from which no appeal is taken within the time allowed for appeal, and that is not still pending seven (7) years from the earliest priority date claimed for such application.

1.50 “VX-745” means Vertex’s small molecule p38 MAP kinase inhibitor known as VX-745.

1.51 “Vertex Patent Rights” means (i) U.S. Patent No. [***], U.S. Patent No. [***]; and (ii) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, and the like, of the foregoing patents or patent applications.

1.52 “Vertex Know-how” means any Know-how owned or otherwise Controlled by Vertex or any of its Affiliates as of the Effective Date that (i) is incorporated into Licensed Product or the manufacturing process for Licensed Product or (ii) was used in, or generated by or on behalf of Vertex in the development, manufacture or use of Licensed Product.

ARTICLE II OPTION GRANT AND RESEARCH LICENSE

2.1 Grant of Option. Vertex hereby grants to EIP an exclusive option, exercisable during the Option Period, to acquire from Vertex the licenses set forth in Section 3.1 (the “License”), subject to the terms and conditions of this Agreement (the “Option”).

2.2 Option Period. The Option will be exercisable by EIP at any time during the period commencing on the Effective Date and ending upon the earlier to occur of (i) six (6) months after the FDA Meeting, or (ii) twenty-four (24) months after the Effective Date (the “Option Period”). During the Option Period, Vertex will not grant a license or other rights to any Third Party, or take any other action, that would prevent Vertex from being able to grant to EIP the License on the terms and conditions set forth in this Agreement.

2.3 Option Exercise. In the event EIP elects to exercise the Option, it shall, no later than the end of the last day of the Option Period, deliver to Vertex (i) written notice specifying that EIP has elected to exercise the Option, (ii) a Development Plan, (iii) evidence of EIP’s resources sufficient to accomplish the Development Plan, including evidence of sufficiently qualified personnel, applicable third party service contracts, and sufficient funding such as a cash balance statement, and (iv) payment of the Option Exercise Fee (collectively, the “Option Exercise Notice”). The date, if any, on which EIP has properly exercised the Option in accordance with this Section 2.3, shall be the “Option Exercise Date” for purposes of this Agreement. The Option Period will be deemed to have ended, and the License Term will be deemed to have commenced, on the Option Exercise Date.

2.4 Research License During Option Period. Subject to the terms and conditions of this Agreement, Vertex hereby grants to EIP and its Affiliates a fully paid-up exclusive license under Vertex Patent Rights and nonexclusive license under Vertex Know-how in each case solely for the conduct of research and pre-clinical development activities related to Licensed Product during the Option Period, as forth on Exhibit B attached hereto (the "Research Plan"), and to manufacture or have manufactured Licensed Product for such activities and in anticipation of future clinical trials, and for no other purpose. For purposes of clarity, EIP will not have the right to conduct any human clinical development activities or commercialize Licensed Product during the Option Period. EIP and its Affiliates will have the right to grant sublicenses under the rights granted to them under this Section 2.4, but solely for but solely for the purposes of having research and pre-clinical development activities conducted by service providers or academic institutions in accordance with the Research Plan, and having Licensed Product manufactured for the purposes contemplated by this Agreement, or otherwise with the written consent of Vertex. Each sublicense granted by EIP pursuant to this Section 2.4 will contain terms and conditions consistent with those sections of this Agreement applicable to Sublicensees. EIP will promptly provide Vertex with a copy of the fully executed sublicense agreement covering any sublicense granted hereunder, and such sublicense agreement will contain the following provisions: (i) a requirement that such Sublicensee comply with the confidentiality provisions and restrictions on use of Confidential Information contained in Article VI with respect to Vertex's Confidential Information, and (ii) an irrevocable grant of ownership or Control to EIP of any and all Know-how IP arising out of the sublicense agreement and any and all Patent Rights directed to such Know-how. If EIP becomes aware of a material breach by a Sublicensee of its obligations under any sublicense, EIP will promptly notify Vertex of the particulars of the same, and will use Commercially Reasonable Efforts to enforce the terms of such sublicense.

2.5 Decision-Making During Option Period. During the Option Period, EIP will have sole decision-making authority with respect to conduct of research and pre-clinical development activities involving Licensed Product and with respect to the manufacture of Licensed Product for EIP's purposes; provided, however, any material change to the Research Plan will require written consent of Vertex.

2.6 Diligence During Option Period. EIP will, itself or through its Affiliates, use Commercially Reasonable Efforts to conduct the activities outlined in the Research Plan, which shall commence within three (3) months of the Effective Date. EIP will hold the FDA Meeting within eighteen (18) months of the Effective Date, and unless the Parties agree otherwise, the failure of EIP to do so shall constitute a material breach of EIP's obligations hereunder.

2.7 Status Updates. Within thirty (30) days of the end of each calendar quarter during the Option Period, EIP will provide to Vertex a written status report describing in reasonable detail to demonstrate EIP's compliance with its diligence obligations hereunder during the Option Period, the status of EIP's research and preclinical development activities related to Licensed Product since the last update.

2.8 Analog Selection. EIP will have the right to select up to ten (10) specific compounds that are analogs to VX-745 to include as back-up compounds under the License to be granted upon EIP's exercise of the Option, provided that (i) each selected analog compound must be described in one or more of claims [***] or claims [***], and (ii) EIP must notify Vertex as to which such analog compounds EIP has selected for inclusion under this Section 2.8 within six (6) months after the Effective Date. The analogs properly selected by EIP under the preceding sentence will be the "Analog" as such term is used in this Agreement without the need for further action by either Party, provided that, at EIP's request, the Parties will execute a letter agreement formally acknowledging the inclusion of the Analog for purposes of this Agreement.

2.9 Know-how Transfer.

2.9.1 **Vertex INDs.** During the Option Period, as set forth in the Technology Transfer Plan, Vertex will provide EIP access, via an electronic data room, to its copies of INDs [***] and [***] (the "Vertex INDs"), the contents of which are listed on Exhibit D attached hereto. The Parties acknowledge that the status of IND [***] with the FDA as of the Effective Date is "withdrawn," and the status of IND [***] with the FDA as of the Effective Date is "inactive." Vertex will, both during the Option Period and during the License Term, timely execute such documents as EIP may reasonably request to transfer the Vertex INDs to EIP or its designee; provided, however Vertex makes no warranties as to the transferability of the Vertex INDs nor as to whether the status of either Vertex IND may be changed, and Vertex is under no obligation to take any action that would cause it to incur expense or unreasonably use Vertex resources, as determined by Vertex in its sole discretion.

2.9.2 **Material and Manufacturing Process.** During the Option Period, as set forth in the Technology Transfer Plan, Vertex will provide EIP such quantities of VX-745, on an as-is basis, as EIP reasonably requires to conduct its activities during the Option Period (limited to quantities that Vertex has on-hand; Vertex will have no obligation to manufacture further quantities of VX-745) on the terms set forth on Exhibit E attached hereto, and a reasonably detailed description of the manufacturing process for Licensed Product, including analytical methods as available and reasonably necessary to allow EIP to establish manufacturing capability so as to be prepared to commence a human clinical trial promptly after the Option Exercise Date.

2.10 Communication between the Parties. Notwithstanding the foregoing or anything contained herein to the contrary, except the notice provisions set forth in Section 11.4, all communication from EIP and its Affiliates to Vertex that is related to this Agreement or Licensed Product will be directed to the individual identified in writing by Vertex as the Alliance Manager (the "Alliance Manager"). EIP agrees that it will not communicate with any employee or contractor of Vertex with regard to any matter under this Agreement or License Product, including any matter related to the transfer of any Vertex Know-how, unless the Alliance Manager has coordinated, or otherwise, granted consent to, such communication. Vertex may replace the Alliance Manager at any time upon written notice to EIP. Vertex will, as needed, on a case by case basis, make Vertex personnel available for direct interaction with EIP both during the Option Period and during the first six months of the License Term in connection with transfer and implementation of the Vertex Know-how.

ARTICLE III
LICENSE GRANTS AND RIGHT OF FIRST REFUSAL

3.1 Vertex Grant to EIP. Subject to the terms and conditions of this Agreement, effective immediately upon the Option Exercise Date, Vertex and its Affiliates grant to EIP an exclusive license under Vertex Patent Rights, and a nonexclusive license under Vertex Know-how, in each case with the right to grant sublicenses to the extent provided in Section 3.2, to research, develop, make, have made, use, import, export, market, offer for sale, sell and have sold Licensed Product in the Territory within the Field.

3.2 Sublicenses.

(a) EIP Rights. The rights granted to EIP by Vertex under the License may be sublicensed, in whole or in part, to a Third Party (through multiple levels of sublicensing) (i) who is providing services to EH) in connection with the manufacture or development of Licensed Product, solely for the purposes of providing such services; or (ii) with the prior written consent of Vertex, which such consent Vertex shall not unreasonably withhold. EIP or any of its Affiliates or permitted Sublicensees may also extend the rights granted under the License to any Affiliate.

(b) Performance by Sublicensees. EIP will be fully responsible for performance by each Sublicensee of its obligations under this Agreement. Each sublicense granted by EIP pursuant to this Section 3.2 will contain terms and conditions consistent with those sections of this Agreement applicable to Sublicensees. EIP will promptly provide Vertex with a copy of the fully executed sublicense agreement covering any sublicense granted hereunder, and such sublicense agreement will contain the following provisions: (i) a requirement that such Sublicensee submit applicable sales or other reports to EIP to the extent necessary or relevant to allow EIP to satisfy all requirements with respect to the content and timing of reports required to be made or records required to be maintained under this Agreement; (ii) an audit requirement consistent with that set forth in Section 4.12; (iii) a requirement that such Sublicensee comply with the confidentiality provisions and restrictions on use of Confidential Information contained in Article VI with respect to Vertex's Confidential Information and (iv) an irrevocable grant of ownership or Control to EIP of any and all Know-how IP arising out of the sublicense agreement and any and all Patent Rights directed to such Know-how. If EIP becomes aware of a material breach by a Sublicensee of its obligations under any sublicense, EIP will promptly notify Vertex of the particulars of the same, and will use Commercially Reasonable Efforts to enforce the terms of such sublicense.

3.3 Know-how Transfer After Option Exercise. After commencement of the License Term, Vertex will transfer to EIP such Vertex Know-how, as set forth in the portion of the Technology Transfer Plan under the heading "License Term Transfer Schedule," which was not previously transferred in accordance with Section 2.9. Timelines for such activities are set forth in the Technology Transfer Plan, or, if none are specified, then within sixty (60) days after the Option Exercise Date.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

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3.4 Decision-Making During the License Term. During the License Term, and subject to EIP's obligations under this Agreement (including Section 3.5 below with respect to diligence), EIP will have sole decision-making authority with respect to the research, development, manufacture, marketing, sale and use of Licensed Product in the Field.

3.5 License Term Diligence.

(a) General. EIP will use Commercially Reasonable Efforts during the License Term to develop and obtain regulatory approval for a Licensed Product in each Major Market, and to promptly and effectively commercialize such Licensed Product in such Major Market if the relevant Marketing Approval is obtained.

(b) Minimum Diligence Requirements. Without limiting the applicability of paragraph (a) of this Section 3.5, EIP will:

(i) Make annual expenditures for development of Licensed Product as set forth in the Development Plan;

(ii) Commence a Phase 2 Clinical Trial of Licensed Product within six (6) months of the Option Exercise Date; and

(iii) Make the First Commercial Sale of Licensed Product in a Major Market within six (6) months of approval in such Major Market.

(c) Commercial Plan. Without limiting the applicability of paragraph (a) of this Section 3.5, EIP shall prepare and submit to Vertex a plan containing the strategy and proposed activities for marketing and selling Licensed Product in the Territory (as updated pursuant to this paragraph (c), the "Commercial Plan"). EIP shall submit a proposed draft of the Commercial Plan to Vertex no later than eighteen (18) months prior to the anticipated First Commercial Sale and shall submit a revised Commercial Plan to Vertex no later than six (6) months prior to the anticipated First Commercial Sale. EIP shall deliver an update of the Commercial Plan from time to time during the Term, and in no case less than once per calendar year. Vertex shall have the opportunity to comment on the proposed draft, revised and updated Commercial Plan and EIP will consider such comments in good faith.

(d) Sales Forecasts. Twelve (12) months prior to the anticipated date of the First Commercial Sale, EIP shall provide Vertex with a non-binding sales forecast which sets forth the projected quarterly sales (by estimated Net Sales) of Licensed Product in the Territory for the twelve (12) month period commencing upon the anticipated First Commercial Sale date. Thereafter, EIP shall provide Vertex with a sales forecast on the first business day of October which sets forth the projected quarterly sales (by estimated Net Sales) of Licensed Product in the Territory for the succeeding calendar year; provided, that, upon the written request of Vertex, EIP shall update quarterly forecasts during the calendar year in which the First Commercial Sale occurs.

(e) Updates and Reports. During the period commencing upon the Option Exercise Date and ending on the First Commercial Sale of a Licensed Product, EIP will provide Vertex with written quarterly updates on the status of development and commercialization activities related to Licensed Product since the last update, including an updated Development Plan and such other information as reasonably needed to demonstrate EIP's compliance with its development diligence obligations hereunder, such reports to be provided no later than thirty (30) days after the conclusion of each calendar quarter. For the period of the License Term following the First Commercial Sale, such reports will be annually updated no later than September 15th.

3.6 Communication. Without limiting the applicability of Sections 2.6 and 3.5, within forty-five (45) days of the Effective Date, the Parties will finalize a schedule upon which a team of representatives from each Party will have a quarterly conference by telephone during the Term to discuss research, development and commercialization activities hereunder and events material to such efforts. EIP shall keep Vertex timely informed of all material events and developments occurring in the course of the research, development and commercialization activities.

3.7 Right of First Refusal.

(a) If during the period commencing on the Option Exercise Date and ending upon Completion of the first Phase 2b Clinical Trial (or Phase 3 Clinical Trial if the FDA Meeting results in approval to progress directly to a Phase 3 Clinical Trial) of Licensed Product after the FDA Meeting, EIP has received a bona fide written offer from a Third Party under which such Third Party proposes to acquire rights to develop and/or commercialize Licensed Product or to acquire ownership of EIP's rights to Licensed Product, including, but not limited to, through a license of development and/or commercialization rights granted under the License for all or a portion of the Territory or a sale or merger of EIP or substantially all of its assets related to Licensed Product, Vertex shall have the right (the "Right of First Refusal") to acquire such rights on the same material financial terms and conditions (including price and form and timing of consideration and rights to be granted) (the "Material Terms") as those offered by the Third Party. Promptly after receipt of a Third Party offer under the preceding sentence, EIP will deliver to Vertex a description of the Material Terms proposed by such Third Party and the identity of such Third Party (the "Offer Notice"). To exercise its Right of First Refusal, Vertex must deliver written notice to EIP within forty-five (45) days of receipt of the Offer Notice, and the Parties will thereafter negotiate in good faith an agreement based on the Material Terms during the following forty-five (45) day period. If Vertex declines to exercise the Right of First Refusal or the Parties are not able, despite good faith negotiations, to consummate a transaction based on the Material Terms within such forty-five (45) day period, EIP will be free to consummate an agreement based on the Material Terms with the Third Party identified in the original Offer Notice or any of its Affiliates (a "Third Party Transaction").

(b) During the six (6) month period commencing upon Completion of the first Phase 2b Clinical Trial (or Phase 3 Clinical Trial if the FDA Meeting results in approval to progress directly to a Phase 3 Clinical Trial) of Licensed Product after the FDA Meeting (the “Vertex Option Period”), Vertex will have the option (the “Reacquisition Option”) to acquire all of the assets of EIP specific to Licensed Product at then current market price and on terms and conditions for acquisition of such assets at a comparable stage of development and market potential. To exercise the Reacquisition Option, Vertex must provide written notice to EIP by the end of the Vertex Option Period. In the event Vertex exercises the Reacquisition Option, but the Parties, after good faith negotiation, are unable to reach agreement on the material terms of the acquisition within sixty (60) days of EIP’s receipt of Vertex’s exercise notice, then one Party may send written notice to the other Party requesting that the Parties meet with a mediator chosen by mutual agreement of the Parties (the “Mediator Request”). If the meeting with the mediator has not occurred within thirty (30) days of the Mediator Request, or if Parties are unable to reach agreement as a result of the meeting with the mediator, then a Party may send written notice to the other Party requesting that the Parties submit to binding arbitration (the “Arbitration Notice”), and, in such event, both Parties agree to submit to binding arbitration with a single arbitrator mutually agreeable to both Parties to establish the financial and other terms of the acquisition based on the requirements set forth in this Section 3.7 (the “Material Terms”). The arbitration will occur within thirty (30) days of the selection of an arbitrator. If the Parties cannot agree on an arbitrator or on the terms of the arbitration, the arbitrator will be selected by the American Arbitration Association (“AAA”) and the rules of the AAA will govern the conduct of the arbitration. The arbitrator’s decision on the Material Terms (the “Final Material Terms”) will be final. Vertex will have no further rights to acquire such assets (other than the licenses set forth in Section 9.4(d) in the event of termination) if Vertex fails to exercise its Reacquisition Option; provided however if Vertex exercised its Reacquisition Option, the Parties submitted to arbitration as described above, and Vertex chose not to enter into an agreement on the Final Material Terms, then EIP will not offer such assets to a Third Party on terms materially less favorable to EIP than the Final Material Terms without first reoffering to Vertex. For the sake of clarity, if a Third Party Transaction that was the subject of Vertex’s Right of First Refusal has been consummated prior to Completion of the first Phase 2b Clinical Trial, then Vertex’s Reacquisition Option shall include the right to assume all rights and obligations of EIP under the terms of such Third Party Transaction specific to Licensed Product.

ARTICLE IV FINANCIAL PROVISIONS

4.1 Option Exercise Fee. In the event PIP elects to exercise the Option, it shall pay to Vertex a non-creditable, non-refundable option exercise fee of [***] (\$[***]) (the “Option Exercise Fee”) on or before the end of the Option Period.

4.2 Milestones Payments by EIP. Subject to the terms and conditions of this Agreement, EIP shall pay Vertex a milestone payment upon the first occurrence of each of the following events with respect to each distinct Licensed Product, no later than five (5) days after the occurrence of the event:

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Event Milestone	Event Milestone Payment
(i) [***]	\$[***]
(ii) [***]	\$[***]
(iii) [***]	\$[***]
(iv) [***]	\$[***]
(v) [***]	\$[***]
(vi) [***]	\$[***]
(vii) [***]	\$[***]

Each of the above milestone payments will be payable only once per distinct Licensed Product, upon the first occurrence of the applicable event, regardless of how many times the event is ultimately achieved for the distinct Licensed Product.

For purposes of the foregoing, a Licensed Product will be deemed to be distinct if it contains a different compound than the compound incorporated into a Licensed Product with respect to which the applicable milestone has already been paid, and not merely a different formulation or mode of administration.

At the time any given milestone payment is due and one or more preceding milestone payments for antecedent milestone events have not been paid, then such unpaid antecedent milestone payments will be due at such time as well.

In addition, EIP will pay to Vertex \$[***] upon the first achievement of Net Sales in excess of \$[***] in any twelve (12) month period.

4.3 Royalty Payments by EIP. Subject to the adjustment, if any, to be made under Sections 4.4 and 4.5, MEP will pay to Vertex royalties on aggregate Net Sales of Licensed Product in the Field in the Territory by EIP and its Affiliates and Sublicensees, as follows:

Portion of Calendar Year Net Sales	Royalty Percentage
[***]	[***]%
[***]	[***]%
[***]	[***]%

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4.4 Royalty Term. Royalties under Section 4.3 for each Licensed Product will be payable on a country-by-country basis during the period commencing on the First Commercial Sale of such Licensed Product in the Field in such country and ending upon the later of (a) the date of expiration, unenforceability or invalidation of the last Valid Claim of Vertex Patent Rights, EIP Product Patent Rights or EIP Background Patent Rights Covering Licensed Product in such country, and (b) ten (10) years from the date of First Commercial Sale in such country (the "Royalty Term"). The royalties payable under Section 4.3 with respect to Net Sales of a Licensed Product will be reduced, on a country by country and Licensed Product-by-Licensed Product basis, to fifty percent (50%) of the amounts otherwise payable under Section 4.3, during any portion of the Royalty Term when there is no Valid Claim of an issued patent within Vertex Patent Rights, MP Product Patent Rights or EIP Background Patent Rights Covering such Licensed Product in the country of sale. Upon expiration of the Royalty Term in the country of sale, each of the licenses granted to EIP and its Affiliates and Sublicenses under Article III will convert to a fully paid-up, non-royalty-bearing, license in the applicable country.

4.5 Third Party Licenses. EIP will have the right to deduct, on a country-by-country basis, from royalties otherwise payable to Vertex under Section 4.3 (after application of the deductions set forth in Section 4.4), fifty percent (50%) of all royalties, upfront fees, milestones and other payments paid by EIP or any of its Affiliates or Sublicenses to Third Parties under licenses to intellectual property or to acquire intellectual property that is necessary for the development, manufacture, import, sale or use of such Licensed Product ("Third-Party Payments"), provided that in no event will the royalty payable to Vertex on Net Sales of Licensed Product be reduced as a result of application of this paragraph, to less than fifty percent (50%) of the royalty determined at the rates set forth in Section 4.3, as reduced by Section 4.4. Amounts available for offset under this Section 4.5 and not used as a credit against royalties in the period incurred may be carried over to future periods until fully utilized. For purposes of this Section 4.5, the term "necessary" shall mean that, in the reasonable determination of EIP, if the relevant Patent Right of the Third Party were to be found to be valid, there would be a high likelihood that the manufacture, use or sale of Licensed Product would be found to infringe such Patent Right, provided that nothing in the foregoing requires a court or other legal determination of validity or infringement.

4.6 Payments; Reports. EIP will pay royalties due on Net Sales in calendar quarter within forty-five (45) days of the end of such calendar quarter. Within twenty (20) days after the end of each calendar quarter for which royalties are payable by EIP under Section 4.3, EIP will submit to Vertex a report, on a country-by-country basis, providing in reasonable detail an accounting of all Net Sales by EIP and its Affiliates and Sublicensees in the Territory (including, in each case, an accounting of all unit sales of the Licensed Product and a calculation of the deductions from gross invoice price to Net Sales in accordance with Section 1.29) made during such calendar quarter and the calculation of the applicable royalties. EIP shall use Commercially Reasonable Efforts to also provide Vertex with a "flash" report of estimated Net Sales only, within five (5) business days after the end of each month during the calendar year. EIP will, at the time EIP submits a royalty report under this Section 4.6, pay to Vertex all amounts due to Vertex under Section 4.3, as indicated in the applicable report.

4.7 Taxes. EIP will make all payments to Vertex under this Agreement without deduction or withholding except to the extent that any such deduction or withholding is required by applicable law to be made on account of Taxes (as that term is defined below). Any Tax required to be withheld under applicable law on amounts payable under this Agreement will promptly be paid by EIP or its Affiliates or Sublicensees on behalf of Vertex to the appropriate governmental authority, and EIP will furnish Vertex with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by Vertex. EIP will give notice of its intention to begin withholding any such Tax in advance and cooperate to use reasonable and legal efforts to reduce such Tax on payments made to Vertex hereunder. The Parties will cooperate with respect to all documentation required by any relevant government taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes. Solely for purposes of this Section 4.7, “Tax” or “Taxes” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by a government authority, but not including EIP income taxes.

4.8 United States Dollars. All dollar (\$) amounts specified in this Agreement are United States dollar amounts.

4.9 Currency Conversion. Neither EIP nor the applicable Sublicensee will change its foreign currency translation methodology without Vertex’s prior written consent. All Payment to be made by EIP to Vertex will be made in U.S. Dollars, to a bank account designated by Vertex. In the case of sales denominated in currencies other than U.S. Dollars, payments will be converted into U.S. Dollars using the quarterly arithmetic average of the relevant calendar quarter’s daily midpoint rates, with a 0% interbank adjustment, as published by OANDA Corporation (www.oanda.com).

4.10 Blocked Payments. If, by reason of applicable laws or regulations in any country, it becomes impossible or illegal for EIP or any of its Affiliates or Sublicensees to move revenues related to Licensed Product out of such country, EIP will promptly notify Vertex of the conditions preventing such transfer, and royalties on the affected Net Sales shall, in lieu of payment under Section 4.6, be deposited in local currency in the relevant country to the credit of Vertex in a recognized banking institution in such county designated by Vertex or, if none is designated by Vertex within a period of thirty (30) days, in a recognized banking institution in such country selected by EIP or its Affiliates or Sublicensees, as the case may be, and identified in a notice given to the Party on whose account the funds are deposited.

4.11 Late Payments. EIP will pay interest to Vertex on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of one percent (1%) per month or the highest rate permitted by applicable law, calculated based on the number of days such payments are paid after the date such payments are due.

4.12 Records and Audits. EIP will keep complete and accurate records relating to the calculations of Net Sales generated in the then current calendar year, and during the preceding three (3) calendar years. Vertex will have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by it and reasonably acceptable to EIP, review any such records of EIP and its Affiliates and Sublicensees (the "Audited Party") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than fourteen (14) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 4.3 within the thirty-six (36) month period preceding the date of the request for review. No calendar year will be subject to audit under this Section 4.12 more than once. EIP will receive a copy of each such report concurrently with receipt by Vertex. Should such inspection lead to the discovery of a discrepancy to Vertex's detriment, LIP will, within thirty (30) days after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy at the rate for late payments set forth in Section 4.11. Vertex will pay the full cost of the review unless the underpayment of royalties is greater than five percent (5%) of the amount due for the entire period being examined, in which case EIP will pay the reasonable cost charged by such accounting firm for such review. Any overpayment of royalties by EIP revealed by an examination will be credited against the amount due in the next following royalty payment from LIP (and any subsequent payments due until the full amount of the overpayment has been recouped).

**ARTICLE V
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION
AND RELATED MATTERS**

5.1 Maintenance of Patent Rights.

(a) Vertex Patent Rights. Vertex shall have the exclusive rights, and the obligation (subject to Vertex's election not to file, prosecute, or maintain pursuant to Section 5.2.1), to diligently maintain (by timely paying all maintenance fees, renewal fees, and other such fees and costs required under applicable laws) the Vertex Patent Rights. Vertex shall be responsible for all patent costs incurred in the maintenance of Vertex Patent Rights during the Option Period. EIP shall reimburse Vertex all patent costs incurred by Vertex in the maintenance of Vertex Patent Rights during the License Term. Vertex shall promptly give reasonable advance notice to EIP of the grant, lapse, revocation, surrender, invalidation or abandonment of any Vertex Patent Rights.

5.2 Option to Maintain Patents.

5.2.1 Vertex shall give notice to EIP of any desire to cease maintenance of Vertex Patent Rights and, in such case, shall permit EIP, at its sole discretion, to continue maintenance of such Vertex Patent Rights at its own expense. If EIP elects to continue maintenance, Vertex shall execute such documents and perform such acts at EIP's expense as may be reasonably necessary to allow EIP to initiate or continue such maintenance.

5.2.2 LIP shall give notice to Vertex of any desire to cease prosecution and/or maintenance of ET Product Patent Rights or EIP Background Patent Rights in any country and, in such case, shall permit Vertex at its sole discretion, to continue prosecution or maintenance of such EIP Product Patent Rights or EIP Background Patent Rights at its own expense. If Vertex elects to continue prosecution or maintenance or to file based on EIP's election not to file pursuant to this Section 5.2, EIP shall execute such documents and perform such acts at Vertex's expense as may be reasonably necessary to allow Vertex to initiate or continue such filing, prosecution or maintenance.

5.3 Re-Examination and Re-Issue.

5.3.1 Vertex shall promptly, but in any case within thirty (30) days of learning of such event, inform RIP of any request for, or filing or declaration of, any re-examination by a Third Party relating to Vertex Patent Rights. EIP and Vertex shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. EIP shall have the right to review and approve any submission to be made in connection with such proceeding.

5.3.2 Vertex shall not initiate any re-examination or re-issue proceeding relating to Vertex Patent Rights without the prior written consent of RIP, which consent shall not be unreasonably withheld.

5.3.3 In connection with any re-issue, or re-examination proceeding relating to Vertex Patent Rights, EIP and Vertex will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Vertex shall keep EIP informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

5.3.4 The expense of any re-examination or re-issue proceeding, and the expense of any opposition or similar two-party proceeding conducted under rules of the U.S. Patent and Trademark Office, or any comparable foreign authority shall, unless agreed otherwise, be treated as maintenance costs pursuant to Section 5.1.

5.4 Patent Term Extensions. Vertex will cooperate, if necessary and appropriate, with EIP in gaining patent term extension (including those extensions available under U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country) wherever applicable to licensed Vertex Patent Rights that Cover Licensed Product in the Territory. All filings for such extensions shall be made by the Party responsible for filing, prosecuting and maintaining the relevant Patent Rights in accordance with this Section 5.4.

5.5 **Enforcement and Defense.**

5.5.1 Each Party shall promptly give the other Party notice of (i) any infringement of Vertex Patent Rights, EIP Background Patent Rights, or RIP Product Patent Rights related to Licensed Product within the Field, or (ii) any misappropriation or misuse of Vertex Know-how or RIP Product Know-how related to Licensed Product within the Field, that may come to the first Party's attention, EIP and Vertex shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both RIP and Vertex, to terminate any such infringement of Vertex Patent Rights, EIP Background Patent Rights, or RIP Product Patent Rights, or any such misappropriation or misuse of Vertex Know-how or EIP Product Know-how, in the Territory. Vertex, upon notice to MP, shall have the first right during the Option Period to initiate and prosecute any such legal action in the name of Vertex and RIP, or to control the defense of any declaratory judgment action, relating to Vertex Patent Rights, or Vertex Know-how in the Territory. EIP, upon notice to Vertex, shall have the first right during the License Term to initiate and prosecute any such legal action in the name of RIP and Vertex, or to control the defense of any declaratory judgment action, relating to EIP Background Patent Rights, RIP Product Patent Rights or RIP Product Know-how in the Territory. The costs of any legal action commenced or the defense of any declaratory judgment in the Territory shall be borne by the Party commencing the legal action. Each Party shall promptly inform the other Party if it elects not to exercise its first right as described above and the other Party shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in its name of and, if necessary, the name of the first Party. Each Party shall have the right to be represented by counsel of its own choice and shall be responsible for paying its own costs.

5.5.2 For any action to terminate any infringement of Vertex Patent Rights, EIP Background Patent Rights, or EIP Product Patent Rights, or any misappropriation or misuse of Vertex Know-how or EIP Product Know-how, as permitted in accordance with Section 5.5.1, in the event that the Party initiating the action is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the first Party to initiate litigation to prosecute and maintain such action. In connection with any such action, EIP and Vertex will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any such action or proceeding, including, to the extent permissible by law, the consultation and approval of any settlement negotiations and the terms of any offer related thereto.

5.5.3 Any recovery obtained by either or both EIP and Vertex in connection with or as a result of any action contemplated by this Section 5.5, whether by settlement or otherwise, shall be shared in order as follows:

- (i) the Party that initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;
- (ii) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and

(iii) the amount of any recovery remaining shall then be allocated between Vertex and EIP as if it were the last Net Sales realized under the terms of this Agreement during the calendar year in which the recovery is paid.

5.5.4 Vertex shall inform EIP of any certification regarding any Vertex Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or its successor provisions or any similar provisions in a country in the Territory and shall provide EIP with a copy of such certification within ten (10) days of receipt. Vertex's and EIP's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Section 5.5; provided, however, that Vertex shall have the first right to initiate and prosecute any action and shall inform EIP of such decision within thirty (30) days, in the case of certification regarding any Vertex Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV), or within a similarly appropriate time in the case of certifications or the like in countries outside of the United States, of receipt of the certification, after which time EIP shall have the right to initiate and prosecute such action.

5.6 Patent Term Restoration. Vertex shall be responsible for obtaining patent term restoration to Vertex Patent Rights. EIP shall be responsible for obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to EIP Product Patent Rights and EIP Background Patent Rights. The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Vertex Patent Rights, EIP Background Patent Rights, and EIP Product Patent Rights. In the event that elections with respect to obtaining such patent term restoration are to be made, Vertex shall have the right to make the election with respect to Vertex Patent Rights and EIP shall have the right to make the election with respect to EIP Product Patent Rights and DP Background Patent Rights.

5.7 Third Party Claims.

5.7.1 If any action, suit or proceeding is brought against EIP or Vertex or any Affiliate or sublicensee of either Party alleging the infringement of the intellectual property rights of a Third Party by reason of the discovery, development, manufacture, use, sale, importation or offer for sale of a Licensed Product in the Territory, EIP shall have the sole right but not the obligation to defend itself and Vertex in such action, suit or proceeding at EIP's sole expense, although Vertex shall have the right to separate counsel at its own expense. The Parties shall cooperate with each other in any defense of any such suit, action or proceeding. The Parties will give each other prompt written notice of the commencement of any such suit, action or proceeding, or receipt of any claim of infringement, and will furnish each other a copy of each communication relating to the alleged infringement. Without regard to which Party defends an infringement claim under this Section 5.7, all damages (including all reasonable costs and expenses associated with any defense of a claim hereunder) associated with any such infringement claim in the Territory shall be borne by EIP.

5.7.2 Neither Party shall compromise, litigate, settle or otherwise dispose of any such suit, action or proceeding without the other Party's advice and prior consent, provided that the Party not having the right to defend the suit shall not unreasonably withhold its consent to any settlement which does not have a material adverse effect on its rights, obligations or benefits, either under this Agreement or otherwise. Notwithstanding the foregoing, if EIP decides to seek a license, EIP may seek to obtain such license for its benefit at its sole cost and expense, provided that the terms and conditions of such license do not include an admission of invalidity of any Vertex Patent Rights, or restrict Vertex's ability to challenge or litigate the validity or applicability of any intellectual property to which the license relates.

5.7.3 The Party first having actual notice of any claim, action or proceeding referenced in Section 5.7.1 above shall promptly notify the other Party in writing, setting forth in reasonable detail, to its knowledge, the facts related to any such claim, action or proceeding. The Parties shall promptly discuss proposed responses to any such matters.

5.8 Patent Marking. EIP agrees to comply with the patent marking statutes in each country in which the Licensed Product is sold by EIP or its Affiliates or Sublicensees.

ARTICLE VI CONFIDENTIALITY

6.1 CONFIDENTIAL INFORMATION. During the Term and for a period of ten (10) years after any termination or expiration of this Agreement, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement (which, in the case of EIP and its Affiliates and Sublicensees, includes activities contemplated by the licenses granted in Sections 2.4 and 3.1) or as otherwise specifically permitted under this Agreement, any Confidential Information of the other Party. The terms of this Agreement will be considered Confidential Information of both Parties, subject to permitted disclosures as set forth in this Article VI. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section 6.1 will not apply to any Confidential Information that:

(i) was known by the receiving Party prior to disclosure by the disclosing Party hereunder or under any previous agreement between the Parties (as evidenced by the receiving Party's written records or other competent evidence);

(ii) is or becomes part of the public domain through no fault of the receiving Party;

(iii) is disclosed to the receiving Party by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party and provided such Third Party is not disclosing such information on behalf of the disclosing Party; or

(iv) is independently developed by personnel of the receiving Party who did not have access to the Confidential Information (as evidenced by the receiving Party's written records or other competent evidence).

In addition, if either Party is required to disclose Confidential Information of the other Party by regulation, law or legal process, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or Nasdaq, such Party shall provide prior written notice and a copy of such intended disclosure to such other Party if possible under the circumstances, will consider in good faith the other Party's interests, will disclose only such Confidential Information of such other Party as is required to be disclosed and will cooperate in the disclosing Party's efforts to obtain a protective order or to limit the scope of the required disclosures. Notwithstanding anything in this Agreement to the contrary, either Party may disclose to bona fide potential investors, lenders, potential acquirors/acquirees, potential and existing collaborators, and to such Party's consultants and advisors, the existence and terms of this Agreement to the extent necessary in connection with a proposed equity or debt financing of such Party, or a proposed acquisition or business combination or transaction, so long as such recipients are bound in writing to maintain the confidentiality of such information.

6.2 Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, consultants and advisors and, in the case of EIP as the receiving Party, to service providers, investigators, Third Party contractors, potential and existing Sublicensees and distributors and potential acquirors, in each case who, in such Party's reasonable judgment, have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement (which, in the case of EIP and its Affiliates and Sublicensees, includes activities contemplated by the license granted in Sections 2.4 and 3.1) or in connection with a potential business relationship or investment that would encompass Licensed Product, and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party under Section 6.1. Vertex and EIP shall each remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants, advisors and permitted contractors, sublicensees and distributors, to treat such Confidential Information as required under Section 6.1 (as if such Affiliates, employees, consultants, advisors, contractors, sublicensees and distributors were Parties directly bound to the requirements of Section 6.1). EIP may also disclose Confidential Information of Vertex to Regulatory Authorities and other governmental authorities, but solely in connection with the activities contemplated by this Agreement.

6.3 Limitation on Vertex Disclosure of Vertex Know-how. During the Term of this Agreement, Vertex will not disclose Vertex Know-how that is specific to the development, manufacture, commercialization or use of Licensed Product (solely to the extent applicable to Licensed Product) to any Third Party without the express written consent of ET, not to be unreasonably withheld.

6.4 Publicity. Neither Party will issue a press release or public announcement relating to the terms of this Agreement without the prior written approval of the other Party, except that (i) a Party may issue such press release or public announcement if the contents of such press release or public announcement are consistent with a previously approved press release or have otherwise previously been made public other than through a breach of this Agreement, and (ii) a Party may issue such a press release or public announcement if required by applicable law, including by the rules or regulations of the United States Securities and Exchange Commission (SEC) or similar regulatory agency in a country other than the United States or of any stock exchange or Nasdaq; provided that such Party complies with the notice and review provisions set forth in this Section 6.4. In no event will either Party make any public disclosure related to EIP's activities under this Agreement or related to the results generated by EIP or any of its Affiliates or Sublicensees with respect to Licensed Product without the prior written consent of the other Party except to the extent required by applicable law. In the event a Party is required by applicable law to publicly disclose any of the results generated by RIP or any of its Affiliates or Sublicensees or any information provided by EIP related to Licensed Product or either Party is required to disclose the terms of this Agreement by applicable law, such Party will give the other Party at least three (3) business days' prior written notice (if possible), will provide to such other Party a copy of the required disclosure, and will consider in good faith comments of such other Party on any such public disclosure.

6.5 Publications.

(a) Option Period. During the Option Period, neither RIP nor Vertex nor any of their Affiliates will publish the results of research or development activities carried out using the Licensed Product without the prior written approval of the other Party, not to be unreasonably withheld.

(b) License Term. During the License Term, EIP and its Affiliates and Sublicensees shall have the sole right to publish the results of development, manufacture, commercialization and use of Licensed Product by MP and its Affiliates and Sublicensees, subject to the following. EIP will submit a draft of any proposed manuscript, abstract or speech to Vertex for comments at least sixty (60) days prior to submission for publication or oral presentation. Vertex shall notify RIP in writing within thirty (30) days of receipt of such draft whether such draft contains (i) information of Vertex that it considers to be confidential under the provisions of Section 6.1 hereof or (ii) information that if published would have an adverse effect on a Vertex patent application covering the subject matter of this Agreement. In any such notification, Vertex shall indicate with specificity its suggestions regarding the manner and degree to which EIP may disclose such information. In the case of item (i) above, EIP may not publish Confidential Information of Vertex without its consent in violation of Section 6.1 of this Agreement. In the case of item (ii) above, Vertex may request a delay and EIP shall delay such publication or presentation, for a period not exceeding ninety (90) days, to permit the timely preparation and filing of a patent application or an application for a certificate of invention covering the information at issue. The Parties agree that authorship of any publication or presentation will be determined based on the customary standards then being applied in the relevant scientific journal or conference. EIP will require any agents conducting the development program on its behalf to comply with publication and presentation restrictions comparable to those set forth herein. The forgoing provisions shall not be interpreted to prevent the publication by a Party of information required by law to be published by that Party.

6.6 Return of Confidential Information. Upon termination of this Agreement other than by expiration of its terms, the receiving Party shall, at the request of, and as directed by, the disclosing Party, return or destroy Confidential Information of the disclosing Party in the receiving Party's possession, and shall destroy any reports or notes in receiving Party's possession to the extent containing the disclosing Party's Confidential Information, and any electronic copies of any of the foregoing, provided that (i) the receiving Party may retain one copy of Confidential Information of the disclosing Party for archival purposes, and (ii) neither Party shall be required to return or destroy copies of the other Party's Confidential Information stored on automatically created system back-up media.

**ARTICLE VII
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS**

7.1 Mutual Representations. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows:

(a) It is duly organized and validly existing under the laws of its jurisdiction of incorporation and has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

(b) The execution, delivery and performance of this Agreement by such Party has been duly and validly authorized and approved by proper corporate action on the part of such Party. Such Party has taken all other action required by applicable law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party.

(c) The execution and delivery of this Agreement, and the performance as contemplated hereunder, by such Party will not violate any applicable law.

(d) Neither the execution and delivery of this Agreement nor the performance hereof by such Party requires such Party to obtain any permit, authorization or consent from any governmental authority (except for any Marketing Approvals, pricing or reimbursement approvals, manufacturing-related approvals or similar approvals necessary for development, manufacture or commercialization of Licensed Products), or from any other person, and such execution, delivery and performance by such Party, including the granting of the licenses granted under this Agreement, will not result in the breach of or give rise to any conflict, termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which such Party may be a party existing as of the Effective Date.

(e) No Debarment. Neither Party nor any of its Affiliates has been debarred or is subject to debarment, and Vertex has, to its actual knowledge, not used in any capacity in connection with the development or manufacture of VX-745 prior to the Effective Date, any person or entity who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or who is the subject of a conviction described in such section.

7.2 Vertex's Representations and Warranties. Vertex hereby makes the following representations and warranties to EIP as of the Effective Date, and covenants to notify EIP during the Option Period of any additional disclosures arising during the Option Period required for the representations and warranties to remain true and correct as of the Option Exercise Date:

(a) Vertex has the right to grant to EIP the rights and licenses described in this Agreement.

(b) Exhibit C contains a complete and correct list of all existing Vertex Patent Rights, existing as of the Effective Date.

(c) To Vertex's actual knowledge, no Third Party is infringing any of the Vertex Patent Rights identified on Exhibit C.

(d) To Vertex's actual knowledge, the making, using or selling of a Licensed Product containing or comprising VX-745 will not infringe any Third Party Patent Rights.

(e) Vertex has not received any written notice of (a) any claim that any patent or trade secret right owned or controlled by a Third Party would be infringed or misappropriated by the manufacture, use, sale, offer for sale or importation of Licensed Products in the Field, or (b) any threatened claims or litigation seeking to invalidate or otherwise challenge the Vertex Patent Rights or Vertex's rights therein.

(f) To Vertex's actual knowledge, Vertex's rights to Vertex Patent Rights are held free and clear of any liens, security interests and similar encumbrances.

(g) The Vertex Patent Rights are not the subject of any interference proceeding known to Vertex, and Vertex is not aware of any pending or threatened action, suit, proceeding or claim by a Third Party challenging Vertex's ownership rights in, or the validity or scope of, the Vertex Patent Rights.

(h) There are no agreements pursuant to which a Third Party has licensed to Vertex ally Vertex Patent Rights or pursuant to which Vertex has otherwise acquired ally Vertex Patent Rights from a Third Party.

(i) To Vertex's actual knowledge, the research, development and manufacture of VX-745 in the Territory on or before the Effective Date has been conducted by Vertex and its Affiliates and its subcontractors in compliance (in all material respects) with all applicable laws.

(j) There have been no inventorship or ownership challenges with respect to any of the Vertex Patent Rights.

(k) Except as set forth, and acknowledged by the Parties, in Section 2.9, neither Vertex nor its Affiliates has received written notice from any Regulatory Authority threatening any proceedings with respect to the research, development or manufacture of any Licensed Product in the Field in the Territory which proceeding is reasonably likely to have a material adverse effect on such research, development, manufacture or use of Licensed Product.

(l) The Vertex Patent Rights that are issued patents have been maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

7.3 EIP's Representations and Warranties. EIP hereby represents and warrants to Vertex as of the Effective Date, and covenants to notify Vertex during the Option Period of any additional disclosures arising during the Option Period required for the representations and warranties to remain true and correct as of the Option Exercise Date, that it has the resources (a) necessary to make Commercially Reasonable Efforts to conduct the activities outlined in the Research Plan as set forth in Section 2.4, which shall commence within three (3) months of the Effective Date, and to hold the FDA Meeting within eighteen (18) months of the Effective Date, and (b) necessary to perform the Development Plan.

7.4 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY HERETO MAKES ANY REPRESENTATIONS AND NEITHER PARTY EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT (INCLUDING ANY LICENSED PRODUCT), INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE. EIP DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF LICENSED PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT, IF COMMERCIALIZED, ANY PARTICULAR SALES LEVEL WILL BE ACHIEVED. VERTEX DISCLAIMS ANY REPRESENTATION OR WARRANTY AS TO THE USE OR TRANSFERABILITY OF THE VERTEX INDS.

ARTICLE VIII INDEMNIFICATION

8.1 Indemnification by EIP. EIP will indemnify, hold harmless, and defend Vertex, its Affiliates, and their respective directors, officers, employees and agents (the "Vertex Indemnitees") from and against any and all damages, liabilities, costs, expenses and amounts paid in settlement (collectively, "Losses") incurred in connection with any Third Party claim to the extent they arise out of or result from, directly or indirectly; (i) any breach of, or inaccuracy in, any representation or warranty made by EIP in this Agreement, or any breach or violation of any term of this Agreement by EIP; (ii) the negligence or willful misconduct of EIP, its Affiliates and their respective Sublicensees, and their respective directors, officers, employees and agents; (iii) the conduct of research activities by or on behalf of EIP during the Option Period; or (iv) in the event EIP exercises its Option, the research, development, manufacture and commercialization of Licensed Product by EIP and its Affiliates and Sublicensees in the Territory under this Agreement. Notwithstanding the foregoing or anything in this Agreement to the contrary, EIP will have no obligation to indemnify the Vertex Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by Vertex in this Agreement; any breach or violation of any term of this Agreement by Vertex; the gross negligence or willful misconduct of any of the Vertex Indemnitees or any other Losses as to which Vertex is obligated to indemnify EIP under Section 8.2.

8.2 Indemnification by Vertex. Vertex will indemnify, hold harmless, and defend EIP, its Affiliates and their respective directors, officers, employees and agents (the “EIP Indemnitees”) from and against any and all Losses incurred in connection with any Third Party claim to the extent they arise out of or result from, directly or indirectly, (i) any breach of, or inaccuracy in, any representation or warranty made by Vertex in this Agreement, or any breach or violation of any term of this Agreement by Vertex; (ii) the gross negligence or willful misconduct of any Vertex Indemnitee; (iii) the research, development, manufacture or use of Licensed Product by or on behalf of Vertex or any of its Affiliates prior to the Effective Date; or (iv) the research, development, manufacture, commercialization, or use of Licensed Product or any other activities of Vertex and its Affiliates and sublicensees outside the Field or outside the Territory. Notwithstanding the foregoing, or anything in this Agreement to the contrary, Vertex will have no obligation to indemnify the EIP Indemnitees for any Losses as to which EIP is obligated to indemnify Vertex under Section 8.1.

8.3 Indemnification Procedure. In the event of any such claim against any EIP Indemnitee or Vertex Indemnitee (individually, an “Indemnitee”), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the defense of the claim and its settlement. The indemnified Party will cooperate with the indemnifying Party and may, at the indemnifying Party’s option and expense, be represented in any such action or proceeding. The indemnifying Party will not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party’s prior written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in this Article 8 may apply, the indemnifying Party will promptly notify the Indemnitees, who shall then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party will be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party.

8.4 Limitation of Liability. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A PARTY'S WILLFUL MISCONDUCT OR A MATERIAL BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE VI. NOTHING IN THIS SECTION 8.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

8.5 Insurance. During the License Term and for a period of at least three (3) years after the last commercial sale of a Licensed Product in the Field under this Agreement, EIP will maintain insurance, with a reputable, solvent insurer in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement, including, commencing immediately prior to the first human clinical trial, product and clinical trial liability insurance of at least \$5,000,000 per occurrence and \$5,000,000 in the aggregate on a worldwide basis.

ARTICLE IX TERM AND TERMINATION

9.1 Term. This term of this Agreement (the "Term") will commence on the Effective Date, and, unless earlier terminated in accordance with this Article IX, will continue until the end of the Option Period, if EIP does not exercise the Option by the end of the Option Period. If EIP exercises the Option in accordance with Article II, this Agreement will continue in full force and effect until expiration of the Royalty Term, unless earlier terminated in accordance with this Article IX. Upon expiration of the Term under the preceding sentence (but not earlier termination of this Agreement) the License will convert to perpetual, fully paid-up, non-royalty-bearing licenses with the same scope.

9.2 Termination for Convenience. EIP will have the right to terminate this Agreement at any time and for any reason upon written notice to Vertex during the Option Period. During the License Term, EIP will have the right to terminate this Agreement at any time and for any reason upon at least ninety (90) days' prior written notice to Vertex if termination occurs prior to receipt of the first Marketing Approval of a Licensed Product and otherwise upon twelve (12) months' prior written notice to Vertex. Following any delivery by EIP of notice of termination pursuant to this Section 9.2, EIP and Vertex will cooperate in good faith to agree and implement a transition plan, in order to give effect to Section 9.4, which plan will include EIP continuing its Commercially Reasonable Efforts to develop, manufacture and commercialize Licensed Products in the Territory as reasonably requested by Vertex to avoid a negative impact, either by its actions or inaction, on the value of a Licensed Product.

9.3 Termination for Cause.

(a) General. Except as limited by paragraph (b), this Agreement may be terminated at any time during the Term:

(i) upon written notice by either Party if the other Party is in material breach of its obligations hereunder, and has not cured such material breach within sixty (60) days after written notice describing the nature of such material breach is provided to the breaching Party; or

(ii) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors, by the other Party; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

(b) Termination to Specific Major Market. Notwithstanding anything to the contrary set forth in this Agreement, in the event of a material breach by EIP of its obligations under Section 3.5 as to a specific Major Market, Vertex's sole remedy under this Agreement for such breach will be, after giving EIP written notice and an opportunity to cure the breach as set forth in paragraph (a), to terminate the License as to such Major Market country. If Vertex terminates this Agreement as to Major Market country under the preceding sentence, the terms "Territory," and "Major Market" as used in this Agreement will, effective upon such termination, be deemed to exclude such country. In the event of any termination as to a Major Market under this paragraph, the Parties will negotiate in good faith the terms of an agreement for sharing adverse event/drug safety information.

9.4 Effect of Termination.

(a) During Option Period. In the event of expiration of this Agreement at the end of the Option Period or earlier termination of this Agreement during the Option Period, other than by EIP for breach by Vertex under Section 9.3(a), EIP will (i) promptly deliver to Vertex all Material-related Know-how and all data generated by or on behalf of EIP related to Licensed Product during the Option Period; and (ii) grant to Vertex and its Affiliates the license set forth in paragraph (d).

(b) During License Term. Upon termination by EIP under Section 9.2, or by Vertex under Section 9.3 EIP will,

(i) assign or otherwise transfer to or at the direction of Vertex as soon as practicable, and at EIP's expense, all filings and approvals with Regulatory Authorities and Marketing Approvals concerning Licensed Products or relating to any Licensed Product;

(ii) prepare promptly and file at Vertex's direction with the appropriate Regulatory Authority or, at Vertex's discretion, made available to or at the direction of Vertex for filing by Vertex, any reports required to be made to any Regulatory Authority covering any periods prior to the effective date of termination of the Agreement;

(iii) promptly deliver to or at the direction of Vertex,

(A) all governmental and regulatory correspondence and conversation logs relating to the development, manufacture or commercialization of Licensed Products in the Territory,

(B) copies of all data, reports, records and materials in Errs possession or Control relating to the development, manufacture or commercialization of Licensed Products in the Territory, including all non-clinical, clinical, and chemistry, manufacturing and controls data relating to Licensed Products,

(C) all safety data and other adverse event data in EIP's possession or Control. EIP will execute all documents, and take all such further actions, as may be reasonably requested by Vertex in order to give effect to the preceding sentence as soon as practicable, and

(D) all Licensed Product bulk drug substance ("API") in its possession.

In connection with the foregoing (1) EIP hereby irrevocably authorizes Vertex to execute any documents to effect any such transfer by EIP and submission by Vertex or Vertex's designee described in this Section and (2) EIP hereby acknowledges and agrees that Vertex shall not be obligated to treat any information received pursuant to this Section as EIP Confidential Information and may use such information, data and know-how for any purpose at Vertex's discretion;

(iv) assign to Vertex all agreements, with respect to the conduct of clinical trials for Licensed Products, including agreements with contract research organizations, clinical sites and investigators, between EIP and any third party, subject to any consent required by such third party, which consent EIP will use commercially reasonable efforts to obtain on behalf of Vertex; and

(v) reimburse Vertex for the cost of Vertex completing all human clinical trials Commenced by EIP but not completed at the time of termination.

(c) Termination as to Major Market. In the event Vertex terminates this Agreement as to a specific Major Market under Section 9.3(b), the above paragraph (b) will apply, provided, that (i) EIP's obligations under such paragraph will be limited to the information, data, reports, records, approvals and agreements specific to such Major Market, and (ii) EIP will continue to have the right to retain any such information, data, reports, records and agreements relevant to the development, manufacture and commercialization of Licensed Product in the remaining countries of the Territory.

(d) Effect of Termination.

(i) In the event of termination of this Agreement by Vertex in its entirety under Section 9.3(a) or termination by MP under Section 9.2 or as a result of MP's failure to exercise the Option during the Option Period, EIP will be deemed to have granted to Vertex a fully paid-up, royalty-free (except as set forth in paragraph (iii)), worldwide, nonexclusive, sublicensable, license under EIP Product Technology and EIP Background Patent Rights to research, develop, make, have made, import, market, sell, have sold and use Licensed Product in the Field.

(ii) In the event that either Party terminates this Agreement pursuant to subsection 9.3(a)(ii), all licenses and rights to licenses granted under or pursuant to this Agreement by the non-terminating Party to other are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that the terminating Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by the other Party under the Code, or against the other Party if such proceeding is not dismissed within ninety (90) days of its initial filing, the terminating Party shall be entitled to complete access to any such intellectual property and all embodiments of such intellectual property in the Territory.

(iii) In the event Vertex terminates this Agreement as to one or more Major Markets under Section 9.3(b), MP will be deemed to have granted to Vertex a fully paid-up, royalty-free (except as set forth in paragraph (iii)), nonexclusive license under EIP Product Technology and EIP Background Patent Rights to develop, make, have made, import, market, sell, have sold, and use Licensed Product in the Field but solely in such Major Markets.

(iv) In the event EIP or any of its Affiliates or Sublicensees is required to make payments to any Third Party by reason of the licenses granted to Vertex under this paragraph (d) or based on the development, manufacture or sale of Licensed Product by or on behalf of Vertex or any of its Affiliates or sublicensees, Vertex may choose to either (a) terminate that portion of its license or activities giving rise to such obligations or (b) pay such amounts due by EIP or any of its Affiliates or Sublicensees to such Third Party by reimbursing EIP or paying such amounts directly to such Third Party, as directed by EIP, in each case based on supporting documentation provided by EIP.

9.5 Survival. Any expiration or termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including payment obligations arising prior to such expiration or termination. The provisions of Articles 1, VI, VIII, IX, X and XI will survive any expiration or termination of this Agreement and all other provisions contained in this Agreement that by their explicit terms survive expiration or termination of this Agreement, will survive. Except as set forth in this Article IX, upon termination or expiration of this Agreement all other rights and obligations of the Parties under this Agreement terminate.

**ARTICLE X
DISPUTE RESOLUTION**

10.1 Referral of Unresolved Matters to Senior Executives. In the event that the Parties are unable to resolve a dispute within fifteen (15) days from the date such dispute is first brought to the other Party's attention, the matter shall be referred to a senior executive of each Party to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral.

10.2 Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement (other than a dispute about terms pursuant to Vertex's exercise of its Reacquisition Option under Section 3.7(b)) that the Parties have not resolved under Section 10.1, will be decided by arbitration in accordance with the Rules of the American Arbitration Association for Commercial Arbitration in effect at the time the dispute arises, unless the Parties hereto mutually agree otherwise. To the extent such rules are inconsistent with this provision, this provision will control. The following rules will apply to any such arbitration:

(a) Any demand for arbitration must be made in writing to the other Party.

(b) There will be one arbitrator mutually selected by the Parties. If the Parties cannot agree on an arbitrator within thirty (30) days, then the AAA shall select the arbitrator. Any arbitration involving patent rights, other intellectual property rights or intellectual property will be heard by an arbitrator who is an expert in such areas.

(c) The arbitration will be held in The Commonwealth of Massachusetts, or such other place as the Parties agree. The arbitrator will apply the substantive law of The Commonwealth of Massachusetts in accordance with Section 11.1, without regard to conflicts of laws and except that the interpretation and enforcement of this arbitration provision will be governed by the Federal Arbitration Act, 9 U.S.C. Section 1 et. seq.

(d) Neither Party will have the right independently to seek recourse from a court of law or other authorities in lieu of arbitration, but each Party has the right before or during the arbitration to seek and obtain from the appropriate court provisional remedies to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration. There shall be a stenographic record of the proceedings. The decision of the arbitrator will be final and binding upon both Parties. The arbitrator will render a written opinion setting forth findings of fact and conclusions of law.

(e) EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

(f) EACH PARTY HERETO WAIVES ANY CLAIM TO PUNITIVE, EXEMPLARY OR MULTIPLIED DAMAGES FROM THE OTHER.

(g) EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL DAMAGES FROM THE OTHER.

(h) The expenses of the arbitration will be borne by the Parties in proportion as to which each Party prevails or is defeated in arbitration. Each Party will bear the expenses of its counsel and other experts,

10.3 Equitable Relief. Notwithstanding anything to the contrary, each of the Parties hereby acknowledges that a breach of their respective obligations under this Agreement may cause irreparable harm and that the remedy or remedies at law for any such breach may be inadequate. Each of the Parties hereby agrees that, in the event of any such breach, in addition to all other available remedies hereunder, the non-breaching Party shall have the right, through the arbitration process described in Section 10.2, to seek equitable relief to enforce the provisions of this Agreement.

ARTICLE XI MISCELLANEOUS

11.1 Governing Law and Jurisdiction. The validity, construction and performance of this Agreement will be governed by and construed in accordance with the substantive laws of The Commonwealth of Massachusetts excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The United Nations Convention on the Sale of Goods shall not apply.

11.2 Force Majeure. Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term, other than an obligation to make payments hereunder, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, acts of God or any other cause beyond the reasonable control of the affected Party to anticipate, prevent, avoid or mitigate (a "**Force Majeure Event**"); provided that (i) the affected Party provides prompt written notice to the other Party of such failure or delay, (ii) the affected Party uses Commercially Reasonable Efforts to mitigate the effects of the Force Majeure Event, and (iii) the affected Party immediately resumes performance upon cessation of the Force Majeure Event. Notwithstanding the foregoing, any failure or delay in fulfilling a term shall not be considered a result of a Force Majeure Event if it arises from a failure of EIP or Vertex to comply with applicable laws.

11.3 Further Assurances. Each Party hereto agrees to perform such acts, execute such further instruments, documents or certificates, and provide such cooperation in proceedings and actions as may be reasonably requested by the other Party in order to carry out the intent and purpose of this Agreement.

11.4 Notices. Any notice required or permitted to be given under this Agreement will be in writing and will be deemed to have been properly given if delivered in person by a internationally recognized overnight courier, or by fax (and promptly confirmed by overnight courier), to the addresses given below or such other addresses as may be designated in writing by the Parties from time to time during the Term.

In the case of EIP:

EIP Pharma LLC
11 Channing Street
Cambridge, MA 02138
Attention: John J. Alam, Manager

With a copy to:

K&L Gates LLP
State Street Financial Center
One Lincoln Street
Boston, MA 02111
Attention: Stephen L. Pahner, Esq.
Fax No.: (617) 261-3175

In the case of Vertex:

Vertex Pharmaceuticals Incorporated
130 Waverly Street
Cambridge, MA 02139
Attention: Senior Vice President, Corporate Strategy and Business Development
Fax No.: (617) 444-7117

With a copy to: General Counsel

11.5 Assignment. This Agreement may not be assigned or otherwise transferred by either Party, without the written consent of the other Party such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that either Party may, without such consent, assign this Agreement, in whole or in part, (i) to any of its Affiliates, and (ii), subject to Section 3.7, either Party, without such consent, may assign its rights and delegate its duties under this Agreement, whether by contract or operation of law, to a Third Party successor or purchaser of all or substantially all of its business or assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other similar transaction, provided that, (i) the Third Party agrees to be bound by the terms of this Agreement, and (ii) Vertex will not assign this Agreement unless the assignee is also assigned ownership or Control of the Vertex Patent Rights and Vertex Know-how. Any purported assignment in violation of this Section 11.5 will be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

11.6 Affiliate Performance. Any obligation of EIP under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at EIP's sole and exclusive option, either by EIP directly or by any Affiliate or permitted Sublicensee of EIP that EIP causes to satisfy, meet or fulfill such obligation, in whole or in part.

11.7 Amendment. The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but only by a written instrument duly executed by both Parties hereto.

11.8 Entire Agreement. This Agreement (including all schedules and exhibits attached hereto) and the MTA, contain the entire understanding of the Parties with respect to the subject matter hereof and supersede all prior agreements, whether written or oral. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. In the event of a conflict between the confidentiality provisions of this Agreement and the MTA, the provisions of this Agreement will govern.

11.9 No Benefit to Third Parties. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons.

11.10 Waiver. The failure of a Party to enforce at any time for any period any of the provisions of this Agreement will not be construed as a waiver of such provisions or of the rights of such Party thereafter to enforce each such provision.

11.11 No Implied Licenses. Except as expressly and specifically provided under this Agreement, the Parties agree that neither Party is granted any implied rights to or under any of the other Party's current or future patents, trade secrets, copyrights, moral rights, trade or service marks, trade dress, or any other intellectual property rights.

11.12 Relationship of the Parties. The Parties agree that their relationship established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically provided in this Agreement, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

11.13 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction in a final unappealable order because it is invalid or conflicts with any law of any relevant jurisdiction, then such provision will be inoperative in such jurisdiction and the remainder of this Agreement shall remain binding upon the Parties hereto.

11.14 Interpretation.

(a) General. Unless the context of this Agreement otherwise requires, (a) words of one gender include the other gender; and (b) words using the singular or plural number also include the plural or singular number, respectively. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days.

(b) Capitalization. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement.

(c) Date References. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

(d) Schedules and Exhibits. All Schedules and Exhibits annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein.

(e) Person References. References to any Person include the successors and permitted assigns of that Person.

(f) References to Parts of this Agreement. References to Articles, Sections, Schedules, and Exhibits are to Articles, Sections, Schedules, and Exhibits of this Agreement unless otherwise specified.

(g) Other Definitional and Interpretative Provisions. The words “hereof”, “herein” and “hereunder” and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Whenever the words “include”, “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation”, whether or not they are in fact followed by those words or words of like import. The word “or” is used in the inclusive sense (and/or) “Writing”, “written” and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form.

(h) Headings. The Article and Section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

(i) Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

11.15 Counterparts. This Agreement may be executed in any number of counterparts (including by facsimile), each of which shall be deemed an original, but all of which together shall constitute one and the same document.

[Signature Page Follows]

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[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

IN WITNESS WHEREOF, EIP and Vertex have caused this Agreement to be duly executed by their authorized representatives under seal, in duplicate on the Effective Date.

EIP PHARMA LLC

By: /s/ John J. Alam, M.D.

Name: John J. Alam, M.D.

Title: Manager

VERTEX PHARMACEUTICALS INCORPORATED

By: /s/ Peter Mueller, Ph.D.

Name: Peter Mueller, Ph.D.

Title: Chief Scientific Officer and Executive Vice President,
Global Research and Development

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Exhibit A

Technology Transfer Plan

[***]

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License Term Technology Transfer Schedule

[***]

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Exhibit B

[***]

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Exhibit C

Vertex Patent Rights

[***]

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Exhibit D

Vertex INDs Summary Document List

[***]

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Exhibit E

Material Transfer Terms

[***]

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[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

AMENDMENT NO. 1**OPTION AND LICENSE AGREEMENT**

This Amendment No. 1 (this "Amendment") to that certain Option and License Agreement by and between EIP Pharma LLC, a Massachusetts limited liability company, with principal offices located at 11 Channing Street, Cambridge, MA 02138 ("EIP") and Vertex Pharmaceuticals Incorporated, a Massachusetts corporation, with principal offices located at 130 Waverly Street, Cambridge, MA 02139 ("Vertex") effective as of August 27, 2012 (the "Option and License Agreement") is effective as of as of April 8, 2014 ("Amendment Effective Date"). Capitalized terms used herein but not defined herein will have the meaning set forth in the Option and Lease Agreement. The Parties agree to amend the Option and License Agreement as follows:

1. To add the following definition:

"Phase 2a Clinical Trial" means a Phase 2 Clinical Trial designed to demonstrate feasibility of a product for an indication.

"Third Party Transaction" means a transaction or series of transactions for the transfer of rights to research, develop and/or commercialize Licensed Product, including, but not limited to, by way of a license, sublicense or assignment.

2. To delete Section 1.20 of the Option and License Agreement in its entirety and replace it with the following text:

"Field" means the diagnosis, treatment, and prevention of Alzheimer's disease and other central nervous system disorders in humans."

3. To delete Section 2.3 of the Option and License Agreement in its entirety and replace it with the following text:

"**2.3 Option Exercise.** In the event EIP elects to exercise the Option, it shall deliver to Vertex (a) no later than the end of the last day of the Option Period, written notice specifying that EIP has elected to exercise the Option, and payment of the Option Exercise Fee and (b) within sixty (60) days of delivery of the foregoing described notice and payment, the Development Plan and evidence of EIP's resources sufficient to accomplish the Development Plan, including evidence of sufficiently qualified personnel, applicable third party service contracts, and sufficient funding such as a cash balance statement (collectively, the "Option Exercise Notice"). The date, if any, on which EIP has delivered the complete Option Exercise Notice is the date on which EIP has exercised the Option in accordance with this Section 2.3 (the "Option Exercise Date"). The Option Period will be deemed to have ended, and the License Term will be deemed to have commenced, on the Option Exercise Date."

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4. To add the following sentence to the end of Section 3.2(b) of the Option and License Agreement:

“For the avoidance of doubt, EIP is fully responsible for payment of all payments due in accordance with Section 4 regardless of whether it has granted a sublicense of any of its rights hereunder.”

5. To delete Section 3.7 of the Option and License Agreement in its entirety and replace it with the following text:

“**3.7 Right of First Refusal.** Commencing on the Option Exercise Date and continuing until six (6) months after Completion of the first Phase 2 Clinical Trial, if EIP receives a bona fide written offer from a Third Party proposing a Third Party Transaction, Vertex shall have the right to acquire such rights on the same material financial terms and conditions, including price and form and timing of consideration and rights to be granted (the “Material Terms”) as those offered by the Third Party. Promptly after receipt of such a Third Party offer, EIP will deliver to Vertex a description of the Material Terms proposed by such Third Party and the identity of such Third Party (the “Offer Notice”). To exercise its Right of First Refusal, Vertex must deliver written notice to EIP within forty-five (45) days of receipt of the Offer Notice, and the Parties will thereafter negotiate in good faith an agreement based on the Material Terms during the following forty-five (45) day period. If Vertex provides notice that it declines to exercise a Right of First Refusal or the Parties are not able, despite good faith negotiations, to consummate a transaction based on the Material Terms within such forty-five (45) day period, EIP will be free to consummate an agreement based on the Material Terms with the Third Party identified in the original Offer Notice or any of its Affiliates.

6. To delete Section 4.1 of the Option and License Agreement in its entirety and replace it with the following text:

“**4.1 Option Exercise Fee.** In the event EIP elects to exercise the Option, it shall pay to Vertex a non-creditable, non-refundable option exercise fee of [***] (\$[***]) (the “Option Exercise Fee”) in accordance with Section 2.3.”

7. To delete Section 4.2 of the Option and License Agreement in its entirety and replace it with the following text:

“**4.2 Milestones Payments by EIP.** Subject to the terms and conditions of this Agreement, EIP shall pay Vertex a milestone payment upon the first occurrence of each of the following events with respect to each distinct Licensed Product, no later than five (5) days after the occurrence of the event:

Event Milestone	Event Milestone Payment
(i) [***]	\$[***]
(ii) [***]	\$[***]
(iii) [***]	\$[***]
(iv) [***]	\$[***]
(v) [***]	\$[***]
(vi) [***]	\$[***]
(vii) [***]	\$[***]
(viii) [***]	\$[***]
(ix) [***]	\$[***]

Each of the above milestone payments will be payable only once per distinct Licensed Product, upon the first occurrence of the applicable event, regardless of how many times the event is ultimately achieved for the distinct Licensed Product.

Milestones (i) and (ii) are mutually exclusive for each distinct Licensed Product such that if milestone (i) occurs, then milestone payment (i) will be due and milestone payment (ii) will not be due; provided, however, if milestone (i) occurs after milestone (ii) occurs then, upon the occurrence of milestone (i), EIP will pay the difference between milestone payment (i) and milestone payment (ii), which was already paid. If neither milestones (i) nor (ii) occur, the payment that would have been due for milestone (ii) will be due at the time the next milestone payment is due. Except as set forth above in this paragraph, at the time any given milestone payment is due and one or more preceding milestone payments for antecedent milestone events have not been paid, then such unpaid antecedent milestone payments will be due at such time as well.

For purposes of the foregoing, a Licensed Product will be deemed to be distinct if it contains a different compound than the compound incorporated into a Licensed Product with respect to which the applicable milestone has already been paid, and not merely a different formulation or mode of administration.

In addition, EIP will pay to Vertex \$[***] upon the first achievement of Net Sales in excess of \$[***] in any twelve (12) month period.”

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

8. To delete Section 4.3 of the Option and License Agreement in its entirety and replace it with the following text:

“**4.3 Royalty Payments by EIP.** Subject to the adjustment, if any, to be made under Sections 4.4 and 4.5, EIP will pay to Vertex royalties on aggregate Net Sales of Licensed Product in the Field in the Territory by EIP and its Affiliates and Sublicensees, as follows:

<u>Portion of Calendar Year Net Sales</u>	<u>Royalty Percentage</u>
[***]	[***]%
[***]	[***]%
[***]	[***]%

9. Except as amended hereby, the terms and conditions of the Option and License Agreement remain in full force and effect.

[signature page immediately follows]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

In witness whereof, EIP and Vertex have caused this Amendment to be duly executed by their authorized representatives under seal, in duplicate as of the Amendment Effective Date.

EIP PHARMA LLC

By: /s/ John J. Alam, M.D.

Name: John J. Alam, M.D.

Title: Manager

VERTEX PHARMACEUTICALS
INCORPORATED

By: /s/ Peter Mueller, Ph.D.

Name: Peter Mueller, Ph.D.

Title: Chief Scientific Officer and Executive Vice President,
Global Research and Development

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[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

AMENDMENT NO. 2**OPTION AND LICENSE AGREEMENT**

This Amendment No. 2 (this "Amendment") to that certain Option and License Agreement by and between EIP Pharma LLC, a Massachusetts limited liability company, with principal offices located at 11 Channing Street, Cambridge, MA 02138 ("EIP") and Vertex Pharmaceuticals Incorporated, a Massachusetts corporation, with principal offices located at 50 Northern Avenue, Boston, MA 02210 ("Vertex") effective as of August 27, 2012, as amended April 18, 2014 (the "Option and License Agreement") is effective as of November 17, 2015 ("Amendment Effective Date"). Capitalized terms used herein but not defined herein will have the meaning set forth in the Option and License Agreement. The Parties agree to amend the Option and License Agreement as follows:

1 To delete Section 4.2 of the Option and License Agreement in its entirety and replace it with the following text:

“4.2 Milestones Payments by EIP. Subject to the terms and conditions of this Agreement, EIP shall pay Vertex a milestone payment upon the first occurrence of each of the following events with respect to each distinct Licensed Product, no later than five (5) days after the occurrence of the event:

Event Milestone	Event Milestone Payment
(i) [***]	\$[***]
(ii) [***]	\$[***]
(iii) [***]	\$[***]
(iv) [***]	\$[***]
(v) [***]	\$[***]
(vi) [***]	\$[***]

Each of the above milestone payments will be payable only once per distinct Licensed Product, upon the first occurrence of the applicable event, regardless of how many times the event is ultimately achieved for the distinct Licensed Product.

For purposes of the foregoing, a Licensed Product will be deemed to be distinct if it contains a different compound than the compound incorporated into a Licensed Product with respect to which the applicable milestone has already been paid, and not merely a different formulation or mode of administration.

In addition, EIP will pay to Vertex \$[***] upon the first achievement of Net Sales in excess of \$[***] in any twelve (12) month period.”

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

2. To delete Section 4.3 of the Option and License Agreement in its entirety and replace it with the following text:

“4.3 Royalty Payments by EIP. Subject to the adjustment, if any, to be made under Sections 4.4 and 4.5, EIP will pay to Vertex royalties on aggregate Net Sales of Licensed Product in the Field in the Territory by EIP and its Affiliates and Sublicensees, as follows:

Portion of Calendar Year Net Sales	Royalty Percentage
***	***%
***	***%
***	***%

3. Except as amended hereby, the terms and conditions of the Option and License Agreement remain in full force and effect.

[signature page immediately follows]

*****] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

In witness whereof, EIP and Vertex have caused this Amendment to be duly executed by their authorized representatives under seal, in duplicate as of the Amendment Effective Date.

EIP PHARMA LLC

By: /s/ John J. Alam, M.D.

Name: John J. Alam, M.D.

Title: Managing Member

VERTEX PHARMACEUTICALS INCORPORATED

By: /s/ Ian Smith

Name: Ian Smith

Title: Chief Financial Officer

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*****] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement"), made and entered into this 2nd day of April, 2018 (the "Effective Date"), by and between EIP Pharma, Inc. ("Company"), and Sylvie Gregoire ("Executive").

WHEREAS, Company wishes to employ Executive as its Executive Chair of the Board of Directors;

WHEREAS, Executive represents that Executive possesses the necessary skills to perform the duties of this position and that Executive has no obligation to any other person or entity which would prevent, limit or interfere with Executive's ability to do so;

WHEREAS, Executive and Company desire to enter into a formal Employment Agreement to assure the harmonious performance of the affairs of Company.

NOW, THEREFORE, in consideration of the mutual promises, terms, provisions, and conditions contained herein, the parties agree as follows:

1. Title and Duties. Subject to the terms and conditions of this Agreement, Company shall employ Executive as its Executive Chair of the Board of Directors ("Board"). Executive accepts such employment upon the terms and conditions set forth herein, and agrees to perform to the best of Executive's ability the duties normally associated with such position and as determined by Company in its reasonable discretion. During Executive's employment, Executive shall devote one-third (1/3) of all of Executive's business time and energies to the business and affairs of Company, provided that nothing contained in this Section 1 shall prevent or limit: (a) Executive's right to manage Executive's personal investments on Executive's own personal time, including, without limitation the right to make passive investments in the securities of (i) any entity which Executive does not control, directly or indirectly, and which does not compete with Company, or (ii) any publicly held entity so long as Executive's aggregate direct and indirect interest does not exceed two percent (2%) of the issued and outstanding securities of any class of securities of such publicly held entity, and (b) so long as such activities do not interfere with Executive's performance of Executive's duties hereunder and do not violate Executive's Covenants Agreement (or similar agreement or policy), Executive's participation: (i) in civic and charitable activities, including as a member of a board of a civic or charitable organization, or (ii) subject to prior written approval from the Board, as a member of a board of a privately-held, for-profit organization.

2. Term of Employment.

(a) Term. Subject to the terms hereof, Executive's employment hereunder shall commence on April 2, 2018 (the "Commencement Date") and shall continue until immediately prior to the consummation of a Qualified Financing (as defined below), *unless* sooner terminated by either party as provided in Section 2(b) (such term of employment referred to herein as the "Term").

For the purposes hereof, “Qualified Financing” means an equity financing pursuant to which the Company sells shares of its preferred stock with (i) an aggregate purchase price of not less than \$20.0 million, (ii) a price per share equal to at least one and one-half times (1.5x) the Series B Original Issue Price (as defined in the Company’s Certificate of Incorporation, as amended) and (iii) the principal purpose of raising capital.

(b) Termination. Notwithstanding anything else contained in this Agreement, Executive’s employment hereunder shall terminate upon the earliest to occur of the following:

(i) Death. Immediately upon Executive’s death;

(ii) Termination by Company.

(A) If because of Executive’s Disability (as defined in Section 2(c)), upon written notice by Company to Executive that Executive’s employment is being terminated as a result of Executive’s Disability, which termination shall be effective on the date of such notice or such later date as specified in writing by Company;

(B) If for Cause (as defined in Section 2(d)), upon written notice by Company to Executive that Executive’s employment is being terminated for Cause, which termination shall be effective on the date of such notice or such later date as specified in writing by Company; or

(C) If by Company for reasons other than Disability or Cause, and pursuant to Section 2(a) above, upon written notice by Company to Executive that Executive’s employment is being terminated, which termination shall be effective thirty (30) days after the date of such notice or such later date as specified in writing by Company.

(iii) Termination by Executive. Upon written notice by Executive to Company that Executive is terminating Executive’s employment, which termination shall be effective at least thirty (30) days after the date of such notice.

Notwithstanding anything in this Section 2(b), Company may at any point terminate Executive’s employment for Cause prior to the effective date of any other termination contemplated hereunder.

(c) Definition of “Disability”. For purposes of this Agreement, “Disability” shall mean Executive’s incapacity or inability to perform Executive’s duties and responsibilities as contemplated herein for ninety (90) days or more within any one (1) year period (cumulative or consecutive), because Executive’s physical or mental health has become so impaired as to make it impossible or impractical for Executive to perform the duties and responsibilities contemplated hereunder. Determination of Executive’s physical or mental health shall be determined by Company after consultation with a medical expert appointed by mutual agreement between Company and Executive who has examined Executive. Executive hereby consents to such examination and consultation regarding Executive’s health and ability to perform as aforesaid.

(d) Definition of "Cause". For purposes of this Agreement, "Cause" shall mean: (i) fraud, embezzlement, or illegal misconduct in connection with the business, operations or affairs of Company; (ii) Executive's commission of, or plea of guilty or *nolo contendere* to, a crime which constitutes a felony; (iii) willful misconduct or gross negligence that is injurious to Company's business, reputation or affairs; (iv) alcohol or substance abuse that materially interferes with the performance by Executive of Executive's duties or obligations; (v) violation of this Agreement or any other material agreement between Executive and Company; (vi) repeated violation of any of the material policies of Company, or a single serious violation of such policies which the Company, in its discretion in either such case, determines is materially injurious to the business or reputation of Company; or (vii) material failure or refusal to perform the duties and obligations delegated to Executive commensurate with Executive's position, which, if capable of being cured, continues after (A) the Company delivers a written notice to Executive describing such failure or refusal, and (B) Executive has failed to cure such failure or refusal after a reasonable time period determined by the Company in its reasonable discretion (not to be less than 30 days).

3. Compensation.

(a) Base Salary. Company shall pay Executive a base salary (the "Base Salary") at the annual rate of One hundred and Eighty Thousand Dollars (\$180,000). The Base Salary shall be payable in substantially equal periodic installments in accordance with Company's payroll practices as in effect from time to time, and in no event less than monthly. Company shall deduct from each such installment all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. The Board or an appropriate committee thereof shall review the Base Salary on an annual basis.

(b) Paid Time Off. Executive may take up to twenty-five (25) days of paid time off ("PTO") per year, to be scheduled to minimize disruption to Company's operations, pursuant to the terms and conditions of Company policy and practices as applied to Company senior executives.

(c) Fringe Benefits. Executive shall be entitled to participate in all benefit/welfare plans and fringe benefits provided to Company senior executives. Executive understands that, except when prohibited by applicable law, Company's benefit plans and fringe benefits may be amended by Company from time to time in its sole discretion.

(d) Reimbursement of Expenses. Company shall reimburse Executive for all ordinary and reasonable out-of-pocket business expenses incurred by Executive in furtherance of Company's business in accordance with Company's policies with respect thereto as in effect from time to time. Executive must submit any request for reimbursement no later than ninety (90) days following the date that such business expense is incurred.

(e) Indemnification. Executive shall be entitled to indemnification with respect to Executive's services provided hereunder pursuant to Delaware law, the terms and conditions of Company's certificate of incorporation and/or by-laws, Company's directors and officers ("D&O") liability insurance policy, and Company's standard indemnification agreement for directors and officers as executed by Company and Executive.

4. Payments Upon Termination.

(a) Definition of Accrued Obligations. For purposes of this Agreement, "Accrued Obligations" means the portion of Executive's Base Salary that has accrued prior to any termination of Executive's employment with Company and has not yet been paid, and the amount of any expenses properly incurred by Executive on behalf of Company prior to any such termination and not yet reimbursed. Executive's entitlement to any other compensation or benefit under any plan of Company shall be governed by and determined in accordance with the terms of such plans, except as otherwise specified in this Agreement.

(b) Termination. If Executive's employment hereunder is terminated, whether by Company, by Executive, or as a result of Executive's Disability or death, then Company shall pay the Accrued Obligations to Executive promptly following the effective date of such termination.

(c) Execution of Separation Agreement. Company shall not be obligated to pay Executive any severance payments or other benefits unless Executive has executed (without revocation) a timely separation agreement in a form acceptable to Company, which shall include a release of claims and standard terms regarding non-disparagement, confidentiality, cooperation and the like, which shall be provided to Executive within ten (10) days following separation from service, and signed by Executive and returned to Company no later than sixty (60) days following Executive's separation from service (the "Review Period").

5. Covenants Agreement. In light of the competitive and proprietary aspects of the business of Company, and as a condition of employment hereunder, Executive agrees to execute and abide by Company's Covenants Agreement.

6. Property and Records. Upon the termination of Executive's employment hereunder, or if Company otherwise requests, Executive shall: (a) return to Company all tangible business information and copies thereof (regardless how such Confidential Information or copies are maintained), and (b) deliver to Company any property of Company which may be in Executive's possession, including, but not limited to, cell phones, smart phones, laptops, products, materials, memoranda, notes, records, reports or other documents or photocopies of the same.

7. Code Sections 409A and 280G.

(a) In the event that the any payments or benefits made to executive upon termination constitute "non-qualified deferred compensation" subject to Section 409A, then the following conditions apply to such payments or benefits:

(i) Any termination of Executive's employment resulting in the payment of any benefits must constitute a "separation from service" under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) before distribution of such benefits can commence. To the extent that the termination of Executive's employment does not constitute a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) (as the result of further services that are reasonably anticipated to be provided by Executive to Company at the time Executive's employment terminates), any such payments that constitute deferred compensation under Section 409A shall be delayed until after the date of a subsequent event constituting a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h). For purposes of clarification, this Section 7(a) shall not cause any forfeiture of benefits on Executive's part, but shall only act as a delay until such time as a "separation from service" occurs.

(ii) Notwithstanding any other provision with respect to the timing of any payments, if, at the time of Executive's termination, Executive is deemed to be a "specified employee" of Company (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then limited only to the extent necessary to comply with the requirements of Section 409A, any payments made to Executive which are subject to Section 409A (and not otherwise exempt from its application) shall be withheld until the first (1st) business day of the seventh (7th) month following the termination of Executive's employment, at which time Executive shall be paid an aggregate amount equal to the accumulated, but unpaid, payments otherwise due to Executive.

(b) It is intended that any payments and benefits provided to Executive upon termination shall be treated as a separate “payment” for purposes of Section 409A. Neither Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(c) Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall be interpreted and at all times administered in a manner that avoids the inclusion of compensation in income under Section 409A, or the payment of increased taxes, excise taxes or other penalties under Section 409A. The parties intend this Agreement to be in compliance with Section 409A. Executive acknowledges and agrees that Company does not guarantee the tax treatment or tax consequences associated with any payment or benefit arising under this Agreement, including but not limited to consequences related to Section 409A.

(d) If any payment or benefit Executive would receive under this Agreement, when combined with any other payment or benefit Executive receives pursuant to a Change of Control (for purposes of this section, a “Payment”) would: (i) constitute a “parachute payment” within the meaning of Section 280G the Code; and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be either: (A) the full amount of such Payment; or (B) such lesser amount as would result in no portion of the Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local employments taxes, income taxes and the Excise Tax, results in Executive’s receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. With respect to subsection (B), if there is more than one method of reducing the payment as would result in no portion of the Payment being subject to the Excise Tax, then Executive shall determine which method shall be followed, provided that if Executive fails to make such determination within thirty (30) days after Company has sent Executive written notice of the need for such reduction, Company may determine the amount of such reduction in its sole discretion.

8. General.

(a) Notices. Except as otherwise specifically provided herein, any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by facsimile transmission upon acknowledgment of receipt of electronic transmission; or (iv) by certified or registered mail, return receipt requested, upon verification of receipt Notices to Executive shall be sent to the last known address in Company’s records or such other address as Executive may specify in writing. Notices to Company shall be sent to:

EIP Pharma, Inc.
210 Broadway, Suite 201
Cambridge, MA 02139
Attn: Attention: Chair, Board of Directors

with a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, MA, 02111
Attn: William C. Hicks, Esq.
Attn: Daniel T. Kajunski, Esq.

(b) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.

(c) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

(d) Assignment. Executive may not assign Executive's rights and obligations under this Agreement without the prior written consent of Company.

(e) Governing Law; Jury Waiver. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the law of Massachusetts without giving effect to the conflict of law principles thereof. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of the Commonwealth of Massachusetts or the United States of America for the District of Massachusetts. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts. ANY ACTION, DEMAND, CLAIM OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT SHALL BE RESOLVED BY A JUDGE ALONE AND EACH OF COMPANY AND EXECUTIVE WAIVES ANY RIGHT TO A JURY TRIAL THEREOF.

(f) Headings and Captions. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify or affect the meaning or construction of any of the terms or provisions hereof.

(g) Entire Agreement. This Agreement, together with the other agreements specifically referenced herein, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

(h) Counterparts. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For all purposes a signature by fax shall be treated as an original.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

SYLVIE GREGOIRE

EIP PHARMA, INC.

/s/ Sylvie Gregoire
Signature
Address:
210 Broadway, Suite 201
Cambridge, MA 02139

By: /s/ John Alam
Name: John Alam
Title: President

[Signature Page to S. Gregoire Executive Employment Agreement]

AMENDMENT NO. 1 TO EXECUTIVE EMPLOYMENT AGREEMENT

This Amendment No. 1 to Executive Employment (the “Amendment”) is made and entered into as of March 4, 2019, by and between EIP Pharma, Inc. (the “Company”) and Sylvie Grégoire (the “Executive”). Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to such terms in that certain Executive Employment Agreement, dated as of April 2, 2018, by and between Company and Executive (the “Agreement”).

WHEREAS, Company and Executive have previously entered into the Agreement and now desire to amend certain provisions of the Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual promises, terms, provisions, and conditions contained herein, the parties agree that the following provisions of the Agreement shall be amended, effective as of the date of this Amendment:

1. Section 1 of the Agreement is hereby deleted in its entirety, and the following is inserted in lieu thereof:

“1. Title and Duties. Subject to the terms and conditions of this Agreement. Company shall employ Executive as its Executive Chair of the Board of Directors (“Board”). Executive accepts such employment upon the terms and conditions set forth herein, and agrees to perform to the best of Executive’s ability the duties normally associated with such position and as determined by Company in its reasonable discretion. During Executive’s employment. Executive shall devote sixty percent (60%) of all of Executive’s business time and energies to the business and affairs of Company. provided that nothing contained in this Section 1 shall prevent or limit: (a) Executive’s right to manage Executive’s personal investments on Executive’s own personal time, including, without limitation the right to make passive investments in the securities of (i) any entity which Executive does not control, directly or indirectly, and which does not compete with Company, or (ii) any publicly held entity so long as Executive’s aggregate direct and indirect interest does not exceed two percent (2%) of the issued and outstanding securities of any class of securities of such publicly held entity, and (h) Executive’s participation (i) in civic and charitable activities, including as a member of a board of a civic or charitable organization, or (ii) subject to prior written approval from the Board, as a member of a board of a privately-held, for-profit organization, provided that such activities do not interfere with Executive’s performance of Executive’s duties hereunder and do not violate Executive’s Covenants Agreement (or similar agreement or policy).”

2. Section 3 of the Agreement is hereby deleted in its entirety, and the following is inserted in lieu thereof:

“3. Compensation.

(a) Base Salary. Company shall pay Executive a base salary (the “Base Salary”) at the annual rate of Three Hundred and Thirty-Three Thousand Seven Hundred and Twenty Dollars (\$333,720). The Base Salary shall be payable in substantially equal periodic installments in accordance with Company’s payroll practices as in effect from time to time, and in no event less than monthly. Company shall deduct from each such installment all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. The Board or an appropriate committee thereof shall review the Base Salary on an annual basis.

(b) Annual Performance Bonus. Executive shall be eligible to receive an annual cash bonus (the “Annual Performance Bonus”), with the target amount of such Annual Performance Bonus equal to Forty Percent (40%) of Executive’s Base Salary in the year to which the Annual Performance Bonus relates, provided that the actual amount of the Annual Performance Bonus may be greater or less than such target amount. The amount of the Annual Performance Bonus shall be determined by the Board or an appropriate committee thereof in its sole discretion, and shall be paid to Executive no later than March 15th of the calendar year immediately following the calendar year in which it was earned. Executive must be employed by Company on the last day of the fiscal year on which the Annual Performance Bonus is based in order to be eligible for such Annual Performance Bonus. Company shall deduct from the Annual Performance Bonus all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. For the current calendar year, Executive shall be eligible for an Annual Performance Bonus at the target amount subject to the terms and conditions described above.

(c) Paid Time Off. Executive may take up to twenty-five (25) days of paid time off (“PTO”) per year, to be scheduled to minimize disruption to Company’s operations, pursuant to the terms and conditions of Company policy and practices as applied to Company senior executives.

(d) Fringe Benefits. Executive shall be entitled to participate in all benefit/welfare plans and fringe benefits provided to Company senior executives. Executive understands that, except when prohibited by applicable law, Company’s benefit plans and fringe benefits may be amended by Company from time to time in its sole discretion.

(e) Reimbursement of Expenses. Company shall reimburse Executive for all ordinary and reasonable out-of-pocket business expenses incurred by Executive in furtherance of Company’s business in accordance with Company’s policies with respect thereto as in effect from time to time. Executive must submit any request for reimbursement no later than ninety (90) days following the date that such business expense is incurred.

(f) Indemnification. Executive shall be entitled to indemnification with respect to Executive’s services provided hereunder pursuant to Delaware law, the terms and conditions of Company’s certificate of incorporation and/or by-laws. Company’s directors and officers (“D&O”) liability insurance policy, and Company’s standard indemnification agreement for directors and officers as executed by Company and Executive.”

3. Except as otherwise set forth herein, the terms and conditions of the Agreement remain unchanged and in full force and effect.

[The Remainder of this Page is Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first set forth above.

EXECUTIVE

By: /s/ Sylvie Grégoire
Name: Sylvie Grégoire

EIP PHARMA, INC.

By: /s/ John J. Alam
Name: John J. Alam
Title: President and Chief Executive Officer

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement"), made and entered into this 2nd day of April, 2018 (the "Effective Date"), by and between EIP Pharma, Inc. ("Company"), and John Alam, M.D. ("Executive").

WHEREAS, Company wishes to employ Executive as its Chief Executive Officer;

WHEREAS, Executive represents that Executive possesses the necessary skills to perform the duties of this position and that Executive has no obligation to any other person or entity which would prevent, limit or interfere with Executive's ability to do so;

WHEREAS, Executive and Company desire to enter into a formal Employment Agreement to assure the harmonious performance of the affairs of Company.

NOW, THEREFORE, in consideration of the mutual promises, terms, provisions, and conditions contained herein, the parties agree as follows:

1. Title and Duties. Subject to the terms and conditions of this Agreement, Company shall employ Executive as its Chief Executive Officer, reporting to Company's Board of Directors ("Board"). Executive accepts such employment upon the terms and conditions set forth herein, and agrees to perform to the best of Executive's ability the duties normally associated with such position and as determined by Company in its reasonable discretion. During Executive's employment, Executive shall devote substantially all of Executive's business time and energies to the business and affairs of Company, provided that nothing contained in this Section 1 shall prevent or limit: (a) Executive's right to manage Executive's personal investments on Executive's own personal time, including, without limitation the right to make passive investments in the securities of (i) any entity which Executive does not control, directly or indirectly, and which does not compete with Company, or (ii) any publicly held entity so long as Executive's aggregate direct and indirect interest does not exceed two percent (2%) of the issued and outstanding securities of any class of securities of such publicly held entity, and (b) so long as such activities do not interfere with Executive's performance of Executive's duties hereunder and do not violate Executive's Covenants Agreement (or similar agreement or policy), Executive's participation: (i) in civic and charitable activities, including as a member of a board of a civic or charitable organization, or (ii) subject to prior written approval from the Board, as a member of a board of a privately-held, for-profit organization.

2. Term of Employment.

(a) Term. Subject to the terms hereof, Executive's employment hereunder shall commence on April 2, 2018 (the "Commencement Date") and shall continue until immediately prior to the consummation of a Qualified Financing (as defined below), *unless* sooner terminated by either party as provided in Section 2(b) (such term of employment referred to herein as the "Term"). For the avoidance of doubt, prior to the consummation of any Qualified Financing, Company and Executive shall negotiate in good faith an amendment to this Agreement containing terms and conditions commensurate with the stage and growth of the Company at such time, including provisions for severance payments to be made to Executive should the amended Agreement be terminated by the Company without Cause (as such term is defined herein or in any amendments to this Agreement) or by the Executive for "good reason."

For the purposes hereof, “Qualified Financing” means an equity financing pursuant to which the Company sells shares of its preferred stock with (i) an aggregate purchase price of not less than \$20.0 million, (ii) a price per share equal to at least one and one-half times (1.5x) the Series B Original Issue Price (as defined in the Company’s Certificate of Incorporation, as amended) and (iii) the principal purpose of raising capital.

(b) Termination. Notwithstanding anything else contained in this Agreement, Executive’s employment hereunder shall terminate upon the earliest to occur of the following:

(i) Death. Immediately upon Executive’s death;

(ii) Termination by Company.

(A) If because of Executive’s Disability (as defined in Section 2(c)), upon written notice by Company to Executive that Executive’s employment is being terminated as a result of Executive’s Disability, which termination shall be effective on the date of such notice or such later date as specified in writing by Company;

(B) If for Cause (as defined in Section 2(d)), upon written notice by Company to Executive that Executive’s employment is being terminated for Cause, which termination shall be effective on the date of such notice or such later date as specified in writing by Company; or

(C) If by Company for reasons other than Disability or Cause, and pursuant to Section 2(a) above, upon written notice by Company to Executive that Executive’s employment is being terminated, which termination shall be effective thirty (30) days after the date of such notice or such later date as specified in writing by Company.

(iii) Termination by Executive. Upon written notice by Executive to Company that Executive is terminating Executive’s employment, which termination shall be effective at least thirty (30) days after the date of such notice.

Notwithstanding anything in this Section 2(b), Company may at any point terminate Executive’s employment for Cause prior to the effective date of any other termination contemplated hereunder.

(c) Definition of “Disability”. For purposes of this Agreement, “Disability” shall mean Executive’s incapacity or inability to perform Executive’s duties and responsibilities as contemplated herein for ninety (90) days or more within any one (1) year period (cumulative or consecutive), because Executive’s physical or mental health has become so impaired as to make it impossible or impractical for Executive to perform the duties and responsibilities contemplated hereunder. Determination of Executive’s physical or mental health shall be determined by Company after consultation with a medical expert appointed by mutual agreement between Company and Executive who has examined Executive. Executive hereby consents to such examination and consultation regarding Executive’s health and ability to perform as aforesaid.

(d) Definition of "Cause". For purposes of this Agreement, "Cause" shall mean: (i) fraud, embezzlement, or illegal misconduct in connection with the business, operations or affairs of Company; (ii) Executive's commission of, or plea of guilty or *nolo contendere* to, a crime which constitutes a felony; (iii) willful misconduct or gross negligence that is injurious to Company's business, reputation or affairs; (iv) alcohol or substance abuse that materially interferes with the performance by Executive of Executive's duties or obligations; (v) violation of this Agreement or any other material agreement between Executive and Company; (vi) repeated violation of any of the material policies of Company, or a single serious violation of such policies which the Company, in its discretion in either such case, determines is materially injurious to the business or reputation of Company; or (vii) material failure or refusal to perform the duties and obligations delegated to Executive commensurate with Executive's position, which, if capable of being cured, continues after (A) the Company delivers a written notice to Executive describing such failure or refusal, and (B) Executive has failed to cure such failure or refusal after a reasonable time period determined by the Company in its reasonable discretion (not to be less than 30 days).

3. Compensation.

(a) Base Salary. Company shall pay Executive a base salary (the "Base Salary") at the annual rate of Four Hundred and Twenty Thousand Dollars (\$420,000). The Base Salary shall be payable in substantially equal periodic installments in accordance with Company's payroll practices as in effect from time to time, and in no event less than monthly. Company shall deduct from each such installment all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. The Board or an appropriate committee thereof shall review the Base Salary on an annual basis.

(b) Annual Performance Bonus. Executive shall be eligible to receive an annual cash bonus (the "Annual Performance Bonus"), with the target amount of such Annual Performance Bonus equal to Forty Percent (40%) of Executive's Base Salary in the year to which the Annual Performance Bonus relates, provided that the actual amount of the Annual Performance Bonus may be greater or less than such target amount. The amount of the Annual Performance Bonus shall be determined by the Board or an appropriate committee thereof in its sole discretion, and shall be paid to Executive no later than March 15th of the calendar year immediately following the calendar year in which it was earned. Executive must be employed by Company on the last day of the fiscal year on which the Annual Performance Bonus is based in order to be eligible for such Annual Performance Bonus. Company shall deduct from the Annual Performance Bonus all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. For the current calendar year, Executive shall be eligible for an Annual Performance Bonus at the target amount subject to the terms and conditions described above.

(c) Paid Time Off. Executive may take up to twenty-five (25) days of paid time off ("PTO") per year, to be scheduled to minimize disruption to Company's operations, pursuant to the terms and conditions of Company policy and practices as applied to Company senior executives.

(d) Fringe Benefits. Executive shall be entitled to participate in all benefit/welfare plans and fringe benefits provided to Company senior executives. Executive understands that, except when prohibited by applicable law, Company's benefit plans and fringe benefits may be amended by Company from time to time in its sole discretion.

(e) Reimbursement of Expenses. Company shall reimburse Executive for all ordinary and reasonable out-of-pocket business expenses incurred by Executive in furtherance of Company's business in accordance with Company's policies with respect thereto as in effect from time to time. Executive must submit any request for reimbursement no later than ninety (90) days following the date that such business expense is incurred.

(f) Indemnification. Executive shall be entitled to indemnification with respect to Executive's services provided hereunder pursuant to Delaware law, the terms and conditions of Company's certificate of incorporation and/or by-laws, Company's directors and officers ("D&O") liability insurance policy, and Company's standard indemnification agreement for directors and officers as executed by Company and Executive.

4. Payments Upon Termination.

(a) Definition of Accrued Obligations. For purposes of this Agreement, "Accrued Obligations" means the portion of Executive's Base Salary that has accrued prior to any termination of Executive's employment with Company and has not yet been paid, and the amount of any expenses properly incurred by Executive on behalf of Company prior to any such termination and not yet reimbursed. Executive's entitlement to any other compensation or benefit under any plan of Company shall be governed by and determined in accordance with the terms of such plans, except as otherwise specified in this Agreement.

(b) Termination. If Executive's employment hereunder is terminated, whether by Company, by Executive, or as a result of Executive's Disability or death, then Company shall pay the Accrued Obligations to Executive promptly following the effective date of such termination.

(c) Execution of Separation Agreement. Company shall not be obligated to pay Executive any severance payments or other benefits unless Executive has executed (without revocation) a timely separation agreement in a form acceptable to Company, which shall include a release of claims and standard terms regarding non-disparagement, confidentiality, cooperation and the like, which shall be provided to Executive within ten (10) days following separation from service, and signed by Executive and returned to Company no later than sixty (60) days following Executive's separation from service (the "Review Period").

5. Covenants Agreement. In light of the competitive and proprietary aspects of the business of Company, and as a condition of employment hereunder, Executive agrees to execute and abide by Company's Covenants Agreement.

6. Property and Records. Upon the termination of Executive's employment hereunder, or if Company otherwise requests, Executive shall: (a) return to Company all tangible business information and copies thereof (regardless how such Confidential Information or copies are maintained), and (b) deliver to Company any property of Company which may be in Executive's possession, including, but not limited to, cell phones, smart phones, laptops, products, materials, memoranda, notes, records, reports or other documents or photocopies of the same.

7. Code Sections 409A and 280G.

(a) In the event that the any payments or benefits made to executive upon termination constitute "non-qualified deferred compensation" subject to Section 409A, then the following conditions apply to such payments or benefits:

(i) Any termination of Executive's employment resulting in the payment of any benefits must constitute a "separation from service" under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) before distribution of such benefits can commence. To the extent that the termination of Executive's employment does not constitute a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) (as the result of further services that are reasonably anticipated to be provided by Executive to Company at the time Executive's employment terminates), any such payments that constitute deferred compensation under Section 409A shall be delayed until after the date of a subsequent event constituting a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h). For purposes of clarification, this Section 7(a) shall not cause any forfeiture of benefits on Executive's part, but shall only act as a delay until such time as a "separation from service" occurs.

(ii) Notwithstanding any other provision with respect to the timing of any payments, if, at the time of Executive's termination, Executive is deemed to be a "specified employee" of Company (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then limited only to the extent necessary to comply with the requirements of Section 409A, any payments made to Executive which are subject to Section 409A (and not otherwise exempt from its application) shall be withheld until the first (1st) business day of the seventh (7th) month following the termination of Executive's employment, at which time Executive shall be paid an aggregate amount equal to the accumulated, but unpaid, payments otherwise due to Executive.

(b) It is intended that any payments and benefits provided to Executive upon termination shall be treated as a separate "payment" for purposes of Section 409A. Neither Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(c) Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall be interpreted and at all times administered in a manner that avoids the inclusion of compensation in income under Section 409A, or the payment of increased taxes, excise taxes or other penalties under Section 409A. The parties intend this Agreement to be in compliance with Section 409A. Executive acknowledges and agrees that Company does not guarantee the tax treatment or tax consequences associated with any payment or benefit arising under this Agreement, including but not limited to consequences related to Section 409A.

(d) If any payment or benefit Executive would receive under this Agreement, when combined with any other payment or benefit Executive receives pursuant to a Change of Control (for purposes of this section, a "Payment") would: (i) constitute a "parachute payment" within the meaning of Section 280G the Code; and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall be either: (A) the full amount of such Payment; or (B) such lesser amount as would result in no portion of the Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. With respect to subsection (B), if there is more than one method of reducing the payment as would result in no portion of the Payment being subject to the Excise Tax, then Executive shall determine which method shall be followed, provided that if Executive fails to make such determination within thirty (30) days after Company has sent Executive written notice of the need for such reduction, Company may determine the amount of such reduction in its sole discretion.

8. General.

(a) Notices. Except as otherwise specifically provided herein, any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by facsimile transmission upon acknowledgment of receipt of electronic transmission; or (iv) by certified or registered mail, return receipt requested, upon verification of receipt Notices to Executive shall be sent to the last known address in Company's records or such other address as Executive may specify in writing. Notices to Company shall be sent to:

EIP Pharma, Inc.
210 Broadway, Suite 201
Cambridge, MA 02139
Attn: Attention: Chair, Board of Directors

with a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, MA, 02111
Attn: William C. Hicks, Esq.
Attn: Daniel T. Kajunski, Esq.

(b) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.

(c) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

(d) Assignment. Executive may not assign Executive's rights and obligations under this Agreement without the prior written consent of Company.

(e) Governing Law; Jury Waiver. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the law of Massachusetts without giving effect to the conflict of law principles thereof. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of the Commonwealth of Massachusetts or the United States of America for the District of Massachusetts. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts. ANY ACTION, DEMAND, CLAIM OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT SHALL BE RESOLVED BY A JUDGE ALONE AND EACH OF COMPANY AND EXECUTIVE WAIVES ANY RIGHT TO A JURY TRIAL THEREOF.

(f) Headings and Captions. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify or affect the meaning or construction of any of the terms or provisions hereof.

(g) Entire Agreement. This Agreement, together with the other agreements specifically referenced herein, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

(h) Counterparts. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For all purposes a signature by fax shall be treated as an original.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

JOHN ALAM, M.D.

EIP PHARMA, INC.

/s/ John Alam
Signature
Address:
210 Broadway, Suite 201
Cambridge, MA 02139

By: /s/ Sylvie Gregoire
Name: Sylvie Gregoire
Title: Secretary

[Signature Page to J. Alam Executive Employment Agreement]



John Alam
President & CEO
EIP Pharma, Inc.

CONFIDENTIAL AND PERSONAL

April 29, 2018

Kelly Blackburn
112 Grove Street
Medford, MA 02155

Dear Kelly:

EIP Pharma, Inc. (the "Company") is pleased to offer you the position of Vice President Clinical Development commencing on or about May 14th, 2018. As Vice President of Clinical Development, you will be reporting to John Alam, President and CEO. You will receive a base salary at the rate of \$180,000 per annum (the "Base Salary"), payable in semi-monthly installments of \$7,500 and subject to applicable deductions and withholdings. You will also be eligible to earn a target bonus of up to 30% of your Base Salary based on achievement of specified performance objectives, payable in cash, as determined in the sole discretion of the Board of Directors of the Company (the "Board"). This position is a part time position, in which you will be expected to devote approximately 60% of your business time and energies to your work for the Company. In your position as Vice President of Clinical Development, you will engage in activities related to achieving the Company's business objectives, as has been described to you by John Alam and other members of the Company's management team.

In addition, subject to the approval of the Board or the Compensation Committee thereof, the Company shall issue to you a non-qualified stock option pursuant to the terms and conditions of the Company's 2018 Employee, Director and Consultant Equity Incentive Plan to purchase 72,000 shares of Common Stock of the Company (the "Common Stock"), at a price per share equal to the fair market value of one share of Common Stock as of the date of grant (the "Option"). The specific terms and conditions of the Option will be determined by the Board or the Compensation Committee thereof, including an expected four year vesting schedule, with (a) one-quarter (1/4) of the shares underlying the Option vesting on the one year anniversary of your actual start date of employment (the "Initial Vest Date") and (b) the remaining three-quarters (3/4) of the shares underlying the Option vesting in equal monthly installments beginning after the Initial Vest Date and continuing over the next thirty-six (36) month period, in all cases subject to your continued employment with the Company.

The Company also offers medical, dental insurance and a 401K plan to its employees, and you will be eligible to participate in these plans in accordance with the Company's policies and eligibility requirements. You should note that the Company may modify salaries, bonuses and benefits, and the rules, terms and conditions for participation therein, from time to time as it deems necessary. Any bonus shall not be considered to be earned until it is paid by the Company.

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You also confirm that this offer is for employment “at will,” which means that you or Company can terminate the employment at any time and for any reason or no reason at all. Although your job duties, title, compensation and benefits, as well as the Company’s personnel policies and procedures, may change from time to time, the “at-will” nature of your employment may only be changed by a written agreement signed by you and an authorized officer of the Company which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company. You will be required, as a condition to employment, to execute an agreement covering nondisclosure, inventions ownership, non-competition, non-solicitation agreement, and other provisions.

In addition, you will be obligated to comply with Company’s standard employee policies and practices in effect from time to time. The Company’s premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.

Any controversy or claim arising out of or relating to your service to the Company, this offer letter, its enforcement or interpretation, or because of an alleged breach, default, or misrepresentation in connection with any of its provisions, shall be submitted by either party to arbitration in Boston, Massachusetts before a single arbitrator (applying Massachusetts law), in accordance with the National Rules for the Resolution of Employment Disputes then in effect of the American Arbitration Association (“AAA”) as modified by the terms and conditions of this offer letter; provided, however, that provisional injunctive relief may, but need not, be sought in a court of law while arbitration proceedings are pending, and any provisional injunctive relief granted by such court shall remain effective until the matter is finally determined by the arbitrator. The arbitrator shall be selected by mutual agreement of the parties or, if the parties cannot agree, by striking from a list of arbitrators supplied by AAA. The arbitrator shall issue a written opinion revealing, however briefly, the essential findings and conclusions upon which the award is based. Final resolution of any dispute through arbitration may include any remedy or relief, which the arbitrator deems just and equitable. Any award or relief granted by the arbitrator hereunder shall be final and binding on the parties hereto and may be enforced by any court of competent jurisdiction. The arbitrator shall have the sole and exclusive power and authority to decide any and all issues of or related to whether this offer letter or any provision of this offer letter. The parties acknowledge that they are hereby waiving any rights to trial by jury in any action, proceeding or counterclaim brought by either of the parties against the other in connection with any matter whatsoever arising out of or in any way connected with this offer letter or your employment.

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This offer letter is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this offer letter or your employment with the Company. No provision of this offer letter may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by you and an authorized officer of the Company. If you agree to the terms of this offer of employment, please sign below and return this letter to me. This offer letter is effective upon signature by you, provided that you sign and return this letter no later than May 11th, 2018, after which time this offer will be withdrawn. We are confident your employment with the Company will prove mutually beneficial, and we look forward to having you join us.

Very truly yours,

John Alam
President & CEO

ACCEPTED BY:

/s/ Kelly Blackburn
Kelly Blackburn

Dated: May 3, 2018

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John Alam
President & CEO
EIP Pharma, Inc.

CONFIDENTIAL AND PERSONAL

January 29, 2019

Kelly Blackburn
112 Grove Street
Medford, MA 02155

Dear Kelly:

EIP Pharma, Inc. (the "Company") is pleased to raise the amount of your base salary to a rate of \$240,000 per annum (the "Base Salary"), payable in semi-monthly installments of \$10,000 and subject to applicable deductions and withholdings. This increase will take effect on February 1st 2019 and you will continue to be eligible to earn a target bonus of up to 30% of your Base Salary based on achievement of specified performance objectives, payable in cash, as determined in the sole discretion of the Board of Directors of the Company (the "Board"). This increase in the Base Salary is being accorded based on the recent discussions you and I have had, in which we have agreed that you would increase your time commitment to the company and going forward would devote approximately 80% of your business time and energies to your work for the Company

In addition, subject to the approval of the Board or the Compensation Committee thereof, the Company shall issue to you an non-qualified stock option pursuant to the terms and conditions of the Company's 2018 Employee, Director and Consultant Equity Incentive Plan to purchase an additional 48,000 shares of Common Stock of the Company (the "Common Stock"), at a price per share equal to the fair market value of one share of Common Stock as of the date of grant (the "Option"). The specific terms and conditions of the Option will be determined by the Board or the Compensation Committee thereof, including an expected four year vesting schedule, with (a) one-quarter (1/4) of the shares underlying the Option vesting on the one year anniversary of February 1st 2019 (the "Initial Vest Date") and (b) the remaining three-quarters (3/4) of the shares underlying the Option vesting in equal monthly installments beginning after the Initial Vest Date and continuing over the next thirty-six (36) month period, in all cases subject to your continued employment with the Company.

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This letter amends the terms in your offer letter dated April 29th, 2018 regarding your base salary and provides an additional stock option grant. All other provisions of that offer letter remain in place.

Very truly yours,

/s/ John Alam
John Alam
President & CEO

ACCEPTED BY:

/s/ Kelly Blackburn
Kelly Blackburn

Date: 29 January 2019

210 Broadway • Suite 201, Second Floor - Cambridge, MA 02139 • O: 617.863.3751

EIP PHARMA, INC.

2018 EMPLOYEE, DIRECTOR AND CONSULTANT EQUITY INCENTIVE PLAN

1. DEFINITIONS.

Unless otherwise specified or unless the context otherwise requires, the following terms, as used in this EIP Pharma, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan, have the following meanings:

Administrator means the Board of Directors, unless it has delegated power to act on its behalf to the Committee, in which case the term "Administrator" means the Committee.

Affiliate means a corporation or other entity which, for purposes of Section 424 of the Code, is a parent or subsidiary of the Company, direct or indirect.

Agreement means an agreement between the Company and a Participant pertaining to a Stock Right delivered pursuant to the Plan, in such form as the Administrator shall approve.

Board of Directors means the Board of Directors of the Company.

California Participant means a Participant who resides in the State of California.

Cause means, with respect to a Participant (a) dishonesty with respect to the Company or any Affiliate, (b) insubordination, substantial malfeasance or non-feasance of duty, (c) unauthorized disclosure of confidential information, (d) breach by a Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or similar agreement between the Participant and the Company or any Affiliate, and (e) conduct substantially prejudicial to the business of the Company or any Affiliate; provided, however, that any provision in an agreement between a Participant and the Company or an Affiliate, which contains a conflicting definition of Cause for termination and which is in effect at the time of such termination, shall supersede this definition with respect to that Participant. The determination of the Administrator as to the existence of Cause will be conclusive on the Participant and the Company.

Code means the United States Internal Revenue Code of 1986, as amended including any successor statute, regulation and guidance thereto.

Committee means the committee of the Board of Directors, if any, to which the Board of Directors has delegated power to act under or pursuant to the provisions of the Plan.

Common Stock means shares of the Company's common stock, \$0.001 par value per share.

Company means EIP Pharma, Inc., a Delaware corporation.

Consultant means any natural person who is an advisor or consultant who provides bona fide services to the Company or its Affiliates, provided that such services are not in connection with the offer or sale of securities in a capital raising transaction, and do not directly or indirectly promote or maintain a market for the Company's or its Affiliates' securities.

Disability or Disabled means permanent and total disability as defined in Section 22(e)(3) of the Code.

Employee means any employee of the Company or of an Affiliate (including, without limitation, an employee who is also serving as an officer or director of the Company or of an Affiliate), designated by the Administrator to be eligible to be granted one or more Stock Rights under the Plan.

Fair Market Value of a Share of Common Stock means:

(1) If the Common Stock is listed on a national securities exchange or traded in the over-the-counter market and sales prices are regularly reported for the Common Stock, the closing or, if not applicable, the last price of the Common Stock on the composite tape or other comparable reporting system for the trading day on the applicable date and if such applicable date is not a trading day, the last market trading day prior to such date;

(2) If the Common Stock is not traded on a national securities exchange but is traded on the over-the-counter market, if sales prices are not regularly reported for the Common Stock for the trading day referred to in clause (1), and if bid and asked prices for the Common Stock are regularly reported, the mean between the bid and the asked price for the Common Stock at the close of trading in the over-the-counter market for the most recent trading day on which Common Stock was traded on the applicable date and if such applicable date is not a trading day, the last market trading day prior to such date; and

(3) If the Common Stock is neither listed on a national securities exchange nor traded in the over-the-counter market, such value as the Administrator, in good faith, shall determine in compliance with applicable laws.

ISO means a stock option intended to qualify as an incentive stock option under Section 422 of the Code.

Non-Qualified Option means a stock option which is not intended to qualify as an ISO.

Option means an ISO or Non-Qualified Option granted under the Plan.

Participant means an Employee, director or Consultant of the Company or an Affiliate to whom one or more Stock Rights are granted under the Plan. As used herein, "Participant" shall include "Participant's Survivors" where the context requires.

Plan means this EIP Pharma, Inc. Employee, Director and Consultant Equity Incentive Plan.

Securities Act means the Securities Act of 1933, as amended.

Shares means shares of the Common Stock as to which Stock Rights have been or may be granted under the Plan or any shares of capital stock into which the Shares are changed or for which they are exchanged within the provisions of Paragraph 3 of the Plan. The Shares issued under the Plan may be authorized and unissued shares or shares held by the Company in its treasury, or both.

Stock-Based Award means a grant by the Company under the Plan of an equity award or an equity based award which is not an Option or a Stock Grant.

Stock Grant means a grant by the Company of Shares under the Plan.

Stock Right means a right to Shares or the value of Shares of the Company granted pursuant to the Plan -- an ISO, a Non-Qualified Option, a Stock Grant or a Stock-Based Award.

Survivor means a deceased Participant's legal representatives and/or any person or persons who acquired the Participant's rights to a Stock Right by will or by the laws of descent and distribution.

2. PURPOSES OF THE PLAN.

The Plan is intended to encourage ownership of Shares by Employees and directors of and certain Consultants to the Company and its Affiliates in order to attract and retain such people, to induce them to work for the benefit of the Company or of an Affiliate and to provide additional incentive for them to promote the success of the Company or of an Affiliate. The Plan provides for the granting of ISOs, Non-Qualified Options, Stock Grants and Stock-Based Awards.

3. SHARES SUBJECT TO THE PLAN.

(a) The number of Shares which may be issued from time to time pursuant to this Plan shall be 1,435,000 shares of Common Stock, or the equivalent of such number of Shares after the Administrator, in its sole discretion, has interpreted the effect of any stock split, stock dividend, combination, recapitalization or similar transaction in accordance with Paragraph 24 of the Plan.

(b) If an Option ceases to be “outstanding”, in whole or in part (other than by exercise), or if the Company shall reacquire at not more than its original issuance price any Shares issued pursuant to a Stock Grant or Stock-Based Award, or if any Stock Right expires or is forfeited, cancelled, or otherwise terminated or results in any Shares not being issued, the unissued or reacquired Shares which were subject to such Stock Right shall again be available for issuance from time to time pursuant to this Plan. Notwithstanding the foregoing, if a Stock Right is exercised, in whole or in part, by tender of Shares or if the Company or an Affiliate’s tax withholding obligation is satisfied by withholding Shares, the number of Shares deemed to have been issued under the Plan for purposes of the limitation set forth in Paragraph 3(a) above shall be the number of Shares that were subject to the Stock Right or portion thereof, and not the net number of Shares actually issued. However, in the case of ISOs, the foregoing provisions shall be subject to any limitations under the Code.

4. ADMINISTRATION OF THE PLAN.

The Administrator of the Plan will be the Board of Directors, except to the extent the Board of Directors delegates its authority to the Committee, in which case the Committee shall be the Administrator. Subject to the provisions of the Plan, the Administrator is authorized to:

(a) Interpret the provisions of the Plan and all Stock Rights and to make all rules and determinations which it deems necessary or advisable for the administration of the Plan;

(b) Determine which Employees, directors and Consultants shall be granted Stock Rights;

(c) Determine the number of Shares for which a Stock Right or Stock Rights shall be granted;

(d) Specify the terms and conditions upon which a Stock Right or Stock Rights may be granted;

(e) Amend any term or condition of any outstanding Stock Right, including, without limitation, to reduce or increase the exercise price or purchase price, accelerate the vesting schedule or extend the expiration date, provided that (i) such term or condition as amended is permitted by the Plan; (ii) any such amendment shall not impair the rights of a Participant under any Stock Right previously granted without such Participant’s consent or in the event of death of the Participant the Participant’s Survivors; and (iii) any such amendment shall be made only after the Administrator determines whether such amendment would cause any adverse tax consequences to the Participant, including, but not limited to, the annual vesting limitation contained in Section 422(d) of the Code and described in Paragraph 6(b)(iv) below with respect to ISOs and pursuant to Section 409A of the Code;

(f) Buy out for a payment in cash or Shares, a Stock Right previously granted and/or cancel any such Stock Right and grant in substitution therefor other Stock Rights, covering the same or a different number of Shares and having an exercise price or purchase price per share which may be lower or higher than the exercise price or purchase price of the cancelled Stock Right, based on such terms and conditions as the Administrator shall establish and the Participant shall accept; and

(g) Adopt any sub-plans applicable to residents of any specified jurisdiction as it deems necessary or appropriate in order to comply with or take advantage of any tax or other laws applicable to the Company, any Affiliate or to Participants or to otherwise facilitate the administration of the Plan, which sub-plans may include additional restrictions or conditions applicable to Stock Rights or Shares issuable pursuant to a Stock Right;

provided, however, that all such interpretations, rules, determinations, terms and conditions shall be made and prescribed in the context of potential tax consequences under Section 409A of the Code and preserving the tax status under Section 422 of the Code of those Options which are designated as ISOs. Subject to the foregoing, the interpretation and construction by the Administrator of any provisions of the Plan or of any Stock Right granted under it shall be final, unless otherwise determined by the Board of Directors, if the Administrator is the Committee. In addition, if the Administrator is the Committee, the Board of Directors may take any action under the Plan that would otherwise be the responsibility of the Committee.

To the extent permitted under applicable law, the Board of Directors or the Committee may allocate all or any portion of its responsibilities and powers to any one or more of its members and may delegate all or any portion of its responsibilities and powers to any other person selected by it. The Board of Directors or the Committee may revoke any such allocation or delegation at any time.

5. ELIGIBILITY FOR PARTICIPATION.

The Administrator will, in its sole discretion, name the Participants in the Plan; provided, however, that each Participant must be an Employee, director or Consultant of the Company or of an Affiliate at the time a Stock Right is granted. Notwithstanding the foregoing, the Administrator may authorize the grant of a Stock Right to a person not then an Employee, director or Consultant of the Company or of an Affiliate; provided, however, that the actual grant of such Stock Right shall be conditioned upon such person becoming eligible to become a Participant at or prior to the time of the execution of the Agreement evidencing such Stock Right. ISOs may be granted only to Employees who are deemed to be residents of the United States for tax purposes. Non-Qualified Options, Stock Grants and Stock-Based Awards may be granted to any Employee, director or Consultant of the Company or an Affiliate. The granting of any Stock Right to any individual shall neither entitle that individual to, nor disqualify him or her from, participation in any other grant of Stock Rights or any grant under any other benefit plan established by the Company or any Affiliate for Employees, directors or Consultants.

6. TERMS AND CONDITIONS OF OPTIONS.

Each Option shall be set forth in writing in an Option Agreement, duly executed by the Company and, to the extent required by law or requested by the Company, by the Participant. The Administrator may provide that Options be granted subject to such terms and conditions, consistent with the terms and conditions specifically required under this Plan, as the Administrator may deem appropriate including, without limitation, subsequent approval by the shareholders of the Company of this Plan or any amendments thereto. The Option Agreements shall be subject to at least the following terms and conditions:

(a) Non-Qualified Options: Each Option intended to be a Non-Qualified Option shall be subject to the terms and conditions which the Administrator determines to be appropriate and in the best interest of the Company, subject to the following minimum standards for any such Non-Qualified Option:

- (i) Exercise Price: Each Option Agreement shall state the exercise price (per share) of the Shares covered by each Option, which exercise price shall be determined by the Administrator and shall be at least equal to the Fair Market Value per share of the Common Stock on the date of grant of the Option.
- (ii) Number of Shares: Each Option Agreement shall state the number of Shares to which it pertains.
- (iii) Vesting Periods: Each Option Agreement shall state the date or dates on which it first is exercisable and the date after which it may no longer be exercised, and may provide that the Option rights accrue or become exercisable in installments over a period of months or years, or upon the occurrence of certain performance conditions or the attainment of stated goals or events. For California Participants, the exercise period of the Option set forth in the Option Agreement shall not be more than 120 months from the date of grant.
- (iv) Additional Conditions: Exercise of any Option may be conditioned upon the Participant's execution of a stockholders agreement in a form satisfactory to the Administrator providing for certain protections for the Company and its other shareholders, including requirements that:
 - A. The Participant's or the Participant's Survivors' right to sell or transfer the Shares may be restricted; and
 - B. The Participant or the Participant's Survivors may be required to execute letters of investment intent and must also acknowledge that the Shares will bear legends noting any applicable restrictions.
- (v) Term of Option: Each Option shall terminate not more than ten years from the date of the grant or at such earlier time as the Option Agreement may provide.

(b) ISOs: Each Option intended to be an ISO shall be issued only to an Employee who is deemed to be a resident of the United States for tax purposes, and shall be subject to the following terms and conditions, with such additional restrictions or changes as the Administrator determines are appropriate but not in conflict with Section 422 of the Code and relevant regulations and rulings of the Internal Revenue Service:

- (i) Minimum standards: The ISO shall meet the minimum standards required of Non-Qualified Options, as described in Paragraph 6(a) above, except subsections (i) and (v) thereunder.

- (ii) Exercise Price: Immediately before the ISO is granted, if the Participant owns, directly or by reason of the applicable attribution rules in Section 424(d) of the Code:
 - A. Ten percent (10%) or less of the total combined voting power of all classes of stock of the Company or an Affiliate, the exercise price per share of the Shares covered by each ISO shall not be less than one hundred percent (100%) of the Fair Market Value per share of the Common Stock on the date of grant of the Option; or
 - B. More than ten percent (10%) of the total combined voting power of all classes of stock of the Company or an Affiliate, the exercise price per share of the Shares covered by each ISO shall not be less than one hundred ten percent (110%) of the Fair Market Value per share of the Common Stock on the date of grant of the Option.
- (iii) Term of Option: For Participants who own:
 - A. Ten percent (10%) or less of the total combined voting power of all classes of stock of the Company or an Affiliate, each ISO shall terminate not more than ten years from the date of the grant or at such earlier time as the Option Agreement may provide; or
 - B. More than ten percent (10%) of the total combined voting power of all classes of stock of the Company or an Affiliate, each ISO shall terminate not more than five (5) years from the date of the grant or at such earlier time as the Option Agreement may provide.
- (iv) Limitation on Yearly Exercise: The Option Agreements shall restrict the amount of ISOs which may become exercisable in any calendar year (under this or any other ISO plan of the Company or an Affiliate) so that the aggregate Fair Market Value (determined on the date each ISO is granted) of the stock with respect to which ISOs are exercisable for the first time by the Participant in any calendar year does not exceed one hundred thousand dollars (\$100,000).

7. TERMS AND CONDITIONS OF STOCK GRANTS.

Each Stock Grant to a Participant shall state the principal terms in an Agreement duly executed by the Company and, to the extent required by law or requested by the Company, by the Participant. For California Participants, each Stock Grant shall be issued within ten (10) years from the earlier of the date the Plan is adopted or approved by the Company's shareholders. The Agreement shall be in a form approved by the Administrator and shall contain terms and conditions which the Administrator determines to be appropriate and in the best interest of the Company, subject to the following minimum standards:

(a) Each Agreement shall state the purchase price per share, if any, of the Shares covered by each Stock Grant, which purchase price shall be determined by the Administrator but shall not be less than the minimum consideration required by the Massachusetts General Corporation Law, if any, on the date of the grant of the Stock Grant;

(b) Each Agreement shall state the number of Shares to which the Stock Grant pertains; and

(c) Each Agreement shall include the terms of any right of the Company to restrict or reacquire the Shares subject to the Stock Grant, including the time and events upon which such rights shall accrue and the purchase price therefor, if any.

8. TERMS AND CONDITIONS OF OTHER STOCK-BASED AWARDS.

The Administrator shall have the right to grant other Stock-Based Awards based upon the Common Stock having such terms and conditions as the Administrator may determine, including, without limitation, the grant of Shares based upon certain conditions, the grant of securities convertible into Shares and the grant of stock appreciation rights, phantom stock awards or stock units. The principal terms of each Stock-Based Award shall be set forth in an Agreement, duly executed by the Company and, to the extent required by law or requested by the Company, by the Participant. The Agreement shall be in a form approved by the Administrator and shall contain terms and conditions which the Administrator determines to be appropriate and in the best interest of the Company. Each Agreement shall include the terms of any right of the Company including the right to terminate the Stock-Based Award without the issuance of Shares, the terms of any vesting conditions or events upon which Shares shall be issued. Under no circumstances may the Agreement covering stock appreciation rights (a) have a base price (per share) that is less than the Fair Market Value per share of Common Stock on the date of grant or (b) expire more than ten years following the date of grant.

The Company intends that the Plan and any Stock-Based Awards granted hereunder be exempt from the application of Section 409A of the Code or meet the requirements of paragraphs (2), (3) and (4) of subsection (a) of Section 409A of the Code, to the extent applicable, and be operated in accordance with Section 409A so that any compensation deferred under any Stock-Based Award (and applicable investment earnings) shall not be included in income under Section 409A of the Code. Any ambiguities in the Plan shall be construed to effect the intent as described in this Paragraph 8.

9. EXERCISE OF OPTIONS AND ISSUE OF SHARES.

An Option (or any part or installment thereof) shall be exercised by giving written notice to the Company or its designee (in a form acceptable to the Administrator, which may include electronic notice), together with provision for payment of the aggregate exercise price in accordance with this Paragraph for the Shares as to which the Option is being exercised, and upon compliance with any other condition(s) set forth in the Option Agreement. Such notice shall be signed by the person exercising the Option (which signature may be provided electronically in a form acceptable to the Administrator), shall state the number of Shares with respect to which the Option is being exercised and shall contain any representation required by the Plan or the Option Agreement. Payment of the exercise price for the Shares as to which such Option is being exercised shall be made (a) in United States dollars in cash or by check, or (b) at the discretion of the Administrator, through delivery of shares of Common Stock held for at least six months (if required to avoid negative accounting treatment) having a Fair Market Value equal as of the date of the exercise to the aggregate cash exercise price for the number of Shares as to which the Option is being exercised, or (c) at the discretion of the Administrator, by having the Company retain from the Shares otherwise issuable upon exercise of the Option, a number of Shares having a Fair Market Value equal as of the date of exercise to the aggregate exercise price for the number of Shares as to which the Option is being exercised, or (d) at the discretion of the Administrator (after consideration of applicable securities, tax and accounting implications), by delivery of the grantee's personal recourse note bearing interest payable not less than annually at no less than one hundred (100%) of the applicable Federal rate, as defined in Section 1274(d) of the Code, or (e) at the discretion of the Administrator, in accordance with a cashless exercise program established with a securities brokerage firm, and approved by the Administrator, or (f) at the discretion of the Administrator, by any combination of (a), (b), (c), (d) and (e) above or (g) at the discretion of the Administrator, by payment of such other lawful consideration as the Administrator may determine. Notwithstanding the foregoing, the Administrator shall accept only such payment on exercise of an ISO as is permitted by Section 422 of the Code.

The Company shall then reasonably promptly deliver the Shares as to which such Option was exercised to the Participant (or to the Participant's Survivors, as the case may be). In determining what constitutes "reasonably promptly," it is expressly understood that the issuance and delivery of the Shares may be delayed by the Company in order to comply with any law or regulation (including, without limitation, state securities or "blue sky" laws) which requires the Company to take any action with respect to the Shares prior to their issuance. The Shares shall, upon delivery, be fully paid, non-assessable Shares.

10. PAYMENT IN CONNECTION WITH THE ISSUANCE OF STOCK GRANTS AND STOCK-BASED AWARDS AND ISSUE OF SHARES.

Any Stock Grant or Stock-Based Award requiring payment of a purchase price for the Shares as to which such Stock Grant or Stock-Based Award is being granted shall be made (a) in United States dollars in cash or by check, or (b) at the discretion of the Administrator, through delivery of shares of Common Stock held for at least six months (if required to avoid negative accounting treatment) and having a Fair Market Value equal as of the date of payment to the purchase price of the Stock Grant or Stock-Based Award, or (c) at the discretion of the Administrator (after consideration of applicable securities, tax and accounting implications), by delivery of the grantee's personal recourse note bearing interest payable not less than annually at no less than one hundred percent (100%) of the applicable Federal rate, as defined in Section 1274(d) of the Code, or (d) at the discretion of the Administrator, by any combination of (a), (b) and (c) above; or (e) at the discretion of the Administrator, by payment of such other lawful consideration as the Administrator may determine.

The Company shall when required by the applicable Agreement, reasonably promptly deliver the Shares as to which such Stock Grant or Stock-Based Award was made to the Participant (or to the Participant's Survivors, as the case may be), subject to any escrow provision set forth in the applicable Agreement. In determining what constitutes "reasonably promptly," it is expressly understood that the issuance and delivery of the Shares may be delayed by the Company in order to comply with any law or regulation (including, without limitation, state securities or "blue sky" laws) which requires the Company to take any action with respect to the Shares prior to their issuance.

11. RIGHTS AS A SHAREHOLDER.

No Participant to whom a Stock Right has been granted shall have rights as a shareholder with respect to any Shares covered by such Stock Right except after due exercise of an Option or issuance of Shares as set forth in any Agreement, tender of the aggregate exercise or purchase price, if any, for the Shares being purchased and registration of the Shares in the Company's share register in the name of the Participant.

12. ASSIGNABILITY AND TRANSFERABILITY OF STOCK RIGHTS.

By its terms, a Stock Right granted to a Participant shall not be transferable by the Participant other than (i) by will or by the laws of descent and distribution, or (ii) as approved by the Administrator in its discretion and set forth in the applicable Agreement, provided that no Stock Right may be transferred by a Participant for value. For California Participants, Stock Rights shall not be transferable by the Participant other than by will or by the laws of descent and distribution, to a revocable trust, or as permitted by Rule 701 of the Securities Act. Notwithstanding the foregoing, an ISO transferred except in compliance with clause (i) above shall no longer qualify as an ISO. The designation of a beneficiary of a Stock Right by a Participant, with the prior approval of the Administrator and in such form as the Administrator shall prescribe, shall not be deemed a transfer prohibited by this Paragraph. Except as provided above during the Participant's lifetime a Stock Right shall only be exercisable by or issued to such Participant (or his or her legal representative) and shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of any Stock Right or of any rights granted thereunder contrary to the provisions of this Plan, or the levy of any attachment or similar process upon a Stock Right, shall be null and void.

13. EFFECT ON OPTIONS OF TERMINATION OF SERVICE OTHER THAN FOR CAUSE OR DEATH OR DISABILITY.

Except as otherwise provided in a Participant's Option Agreement, in the event of a termination of service (whether as an Employee, director or Consultant) with the Company or an Affiliate before the Participant has exercised an Option, the following rules apply:

(a) A Participant who ceases to be an Employee, director or Consultant of the Company or of an Affiliate (for any reason other than termination for Cause, Disability, or death for which events there are special rules in Paragraphs 14, 15, and 16, respectively), may exercise any Option granted to him or her to the extent that the Option is exercisable on the date of such termination of service, but only within such term as the Administrator has designated in a Participant's Option Agreement. For Options granted to California Participants, notwithstanding the terms of any Option Agreement, such Option shall be exercisable for at least thirty (30) days from the date of a Participant's termination of employment other than for Cause, but in no event later than the originally prescribed term of the Option.

(b) Except as provided in Subparagraph (c) below, or Paragraph 15 or 16, in no event may an Option intended to be an ISO, be exercised later than three months after the Participant's termination of employment.

(c) The provisions of this Paragraph, and not the provisions of Paragraph 15 or 16, shall apply to a Participant who subsequently becomes Disabled or dies after the termination of employment, director status or consultancy; provided, however, in the case of a Participant's Disability or death within three months after the termination of employment, director status or consultancy, the Participant or the Participant's Survivors may exercise the Option within one year after the date of the Participant's termination of service, but in no event after the date of expiration of the term of the Option.

(d) Notwithstanding anything herein to the contrary, if subsequent to a Participant's termination of employment, termination of director status or termination of consultancy, but prior to the exercise of an Option, the Administrator determines that, either prior or subsequent to the Participant's termination, the Participant engaged in conduct which would constitute Cause, then such Participant shall forthwith cease to have any right to exercise any Option.

(e) A Participant to whom an Option has been granted under the Plan who is absent from the Company or an Affiliate because of temporary disability (any disability other than a Disability as defined in Paragraph 1 hereof), or who is on leave of absence for any purpose, shall not, during the period of any such absence, be deemed, by virtue of such absence alone, to have terminated such Participant's employment, director status or consultancy with the Company or with an Affiliate, except as the Administrator may otherwise expressly provide; provided, however, that, for ISOs, any leave of absence granted by the Administrator of greater than three months, unless pursuant to a contract or statute that guarantees the right to reemployment, shall cause such ISO to become a Non-Qualified Option on the date that is six months following the commencement of such leave of absence.

(f) Except as required by law or as set forth in a Participant's Option Agreement, Options granted under the Plan shall not be affected by any change of a Participant's status within or among the Company and any Affiliates, so long as the Participant continues to be an Employee, director or Consultant of the Company or any Affiliate.

14. EFFECT ON OPTIONS OF TERMINATION OF SERVICE FOR CAUSE.

Except as otherwise provided in a Participant's Option Agreement, the following rules apply if the Participant's service (whether as an Employee, director or Consultant) with the Company or an Affiliate is terminated for Cause prior to the time that all of his or her outstanding Options have been exercised:

(a) All outstanding and unexercised Options as of the time the Participant is notified his or her service is terminated for Cause will immediately be forfeited.

(b) Cause is not limited to events which have occurred prior to a Participant's termination of service, nor is it necessary that the Administrator's finding of Cause occur prior to termination. If the Administrator determines, subsequent to a Participant's termination of service but prior to the exercise of an Option, that either prior or subsequent to the Participant's termination the Participant engaged in conduct which would constitute Cause, then the right to exercise any Option is forfeited.

15. EFFECT ON OPTIONS OF TERMINATION OF SERVICE FOR DISABILITY.

Except as otherwise provided in a Participant's Option Agreement,

(a) A Participant who ceases to be an Employee, director or Consultant of the Company or of an Affiliate by reason of Disability may exercise any Option granted to such Participant:

- (i) To the extent that the Option has become exercisable but has not been exercised on the date of the Participant's termination of service due to Disability; and
- (ii) In the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of the Participant's termination of service due to Disability of any additional vesting rights that would have accrued on the next vesting date had the Participant not become Disabled. The proration shall be based upon the number of days accrued in the current vesting period prior to the date of the Participant's termination of service due to Disability.

(b) A Disabled Participant may exercise the Option only within the period ending one year after the date of the Participant's termination of service due to Disability, notwithstanding that the Participant might have been able to exercise the Option as to some or all of the Shares on a later date if the Participant had not been terminated due to Disability and had continued to be an Employee, director or Consultant or, if earlier, within the originally prescribed term of the Option. Notwithstanding the terms of any Option Agreement, for Options granted to California Participants, a Participant may exercise such rights for at least six (6) months from the date of termination of service due to Disability but in no event later than the originally prescribed term of the Option.

(c) The Administrator shall make the determination both of whether Disability has occurred and the date of its occurrence (unless a procedure for such determination is set forth in another agreement between the Company and such Participant, in which case such procedure shall be used for such determination). If requested, the Participant shall be examined by a physician selected or approved by the Administrator, the cost of which examination shall be paid for by the Company.

16. EFFECT ON OPTIONS OF DEATH WHILE AN EMPLOYEE, DIRECTOR OR CONSULTANT.

Except as otherwise provided in a Participant's Option Agreement,

(a) In the event of the death of a Participant while the Participant is an Employee, director or Consultant of the Company or of an Affiliate, such Option may be exercised by the Participant's Survivors:

- (i) To the extent that the Option has become exercisable but has not been exercised on the date of death; and
- (ii) In the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of death of any additional vesting rights that would have accrued on the next vesting date had the Participant not died. The proration shall be based upon the number of days accrued in the current vesting period prior to the Participant's date of death.

(b) If the Participant's Survivors wish to exercise the Option, they must take all necessary steps to exercise the Option within one year after the date of death of such Participant, notwithstanding that the decedent might have been able to exercise the Option as to some or all of the Shares on a later date if he or she had not died and had continued to be an Employee, director or Consultant or, if earlier, within the originally prescribed term of the Option.

17. EFFECT OF TERMINATION OF SERVICE ON UNACCEPTED STOCK GRANTS AND STOCK-BASED AWARDS.

In the event of a termination of service (whether as an Employee, director or Consultant) with the Company or an Affiliate for any reason before the Participant has accepted a Stock Grant or a Stock-Based Award and paid the purchase price, if required at the time, such grant shall terminate.

For purposes of this Paragraph 17 and Paragraph 18 below, a Participant to whom a Stock Grant or a Stock-Based Award has been issued under the Plan who is absent from work with the Company or with an Affiliate because of temporary disability (any disability other than a Disability as defined in Paragraph 1 hereof), or who is on leave of absence for any purpose, shall not, during the period of any such absence, be deemed, by virtue of such absence alone, to have terminated such Participant's employment, director status or consultancy with the Company or with an Affiliate, except as the Administrator may otherwise expressly provide.

In addition, for purposes of this Paragraph 17 and Paragraph 18 below, any change of employment or other service within or among the Company and any Affiliates shall not be treated as a termination of employment, director status or consultancy so long as the Participant continues to be an Employee, director or Consultant of the Company or any Affiliate.

18. EFFECT ON STOCK GRANTS AND STOCK-BASED AWARDS OF TERMINATION OF SERVICE OTHER THAN FOR CAUSE, DEATH OR DISABILITY.

Except as otherwise provided in a Participant's Agreement, in the event of a termination of service (whether as an Employee, director or Consultant), other than termination for Cause, death or Disability for which events there are special rules in Paragraphs 19, 20, and 21, respectively, before all forfeiture provisions or Company rights of repurchase shall have lapsed, then the Company shall have the right to cancel or repurchase that number of Shares subject to a Stock Grant or Stock-Based Award as to which the Company's forfeiture or repurchase rights have not lapsed.

19. EFFECT ON STOCK GRANTS AND STOCK-BASED AWARDS OF TERMINATION OF SERVICE FOR CAUSE.

Except as otherwise provided in a Participant's Agreement, the following rules apply if the Participant's service (whether as an Employee, director or Consultant) with the Company or an Affiliate is terminated for Cause:

(a) All Shares subject to any Stock Grant or Stock-Based Award whether or not then subject to forfeiture or repurchase shall be immediately subject to repurchase by the Company at the lesser of Fair Market Value or the purchase price thereof.¹

(b) Cause is not limited to events which have occurred prior to a Participant's termination of service, nor is it necessary that the Administrator's finding of Cause occur prior to termination. If the Administrator determines, subsequent to a Participant's termination of service, that either prior or subsequent to the Participant's termination the Participant engaged in conduct which would constitute Cause, then all Shares subject to any Stock Grant or Stock-Based Award that remained subject to forfeiture provisions or as to which the Company had a repurchase right on the date of termination shall be immediately forfeited to the Company.

20. EFFECT ON STOCK GRANTS AND STOCK-BASED AWARDS OF TERMINATION OF SERVICE FOR DISABILITY.

Except as otherwise provided in a Participant's Agreement, the following rules apply if a Participant ceases to be an Employee, director or Consultant of the Company or of an Affiliate by reason of Disability: to the extent the forfeiture provisions or the Company's rights of repurchase have not lapsed on the date of Disability, they shall be exercisable; provided, however, that in the event such forfeiture provisions or rights of repurchase lapse periodically, such provisions or rights shall lapse to the extent of a pro rata portion of the Shares subject to such Stock Grant or Stock-Based Award through the date of Disability as would have lapsed had the Participant not become Disabled. The proration shall be based upon the number of days accrued prior to the date of Disability.

The Administrator shall make the determination both as to whether Disability has occurred and the date of its occurrence (unless a procedure for such determination is set forth in another agreement between the Company and such Participant, in which case such procedure shall be used for such determination). If requested, the Participant shall be examined by a physician selected or approved by the Administrator, the cost of which examination shall be paid for by the Company.

21. EFFECT ON STOCK GRANTS AND STOCK-BASED AWARDS OF DEATH WHILE AN EMPLOYEE, DIRECTOR OR CONSULTANT.

Except as otherwise provided in a Participant's Agreement, the following rules apply in the event of the death of a Participant while the Participant is an Employee, director or Consultant of the Company or of an Affiliate: to the extent the forfeiture provisions or the Company's rights of repurchase have not lapsed on the date of death, they shall be exercisable; provided, however, that in the event such forfeiture provisions or rights of repurchase lapse periodically, such provisions or rights shall lapse to the extent of a pro rata portion of the Shares subject to such Stock Grant or Stock-Based Award through the date of death as would have lapsed had the Participant not died. The proration shall be based upon the number of days accrued prior to the Participant's date of death.

22. PURCHASE FOR INVESTMENT.

Unless the offering and sale of the Shares shall have been effectively registered under the Securities Act, the Company shall be under no obligation to issue Shares under the Plan unless and until the following conditions have been fulfilled:

(a) The person who receives a Stock Right shall warrant to the Company, prior to the receipt of Shares, that such person is acquiring such Shares for his or her own account, for investment, and not with a view to, or for sale in connection with, the distribution of any such Shares, in which event the person acquiring such Shares shall be bound by the provisions of the following legend (or a legend in substantially similar form) which shall be endorsed upon the certificate evidencing the Shares issued pursuant to such exercise or such grant:

“The shares represented by this certificate have been taken for investment and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a Registration Statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Company shall have received an opinion of counsel satisfactory to it that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable state securities laws.”

(b) At the discretion of the Administrator, the Company shall have received an opinion of its counsel that the Shares may be issued in compliance with the Securities Act without registration thereunder.

23. DISSOLUTION OR LIQUIDATION OF THE COMPANY.

Upon the dissolution or liquidation of the Company, all Options granted under this Plan which as of such date shall not have been exercised and all Stock Grants and Stock-Based Awards which have not been accepted, to the extent required under the applicable Agreement, will terminate and become null and void; provided, however, that if the rights of a Participant or a Participant's Survivors have not otherwise terminated and expired, the Participant or the Participant's Survivors will have the right immediately prior to such dissolution or liquidation to exercise or accept any Stock Right to the extent that the Stock Right is exercisable or subject to acceptance as of the date immediately prior to such dissolution or liquidation. Upon the dissolution or liquidation of the Company, any outstanding Stock-Based Awards shall immediately terminate unless otherwise determined by the Administrator or specifically provided in the applicable Agreement.

24. ADJUSTMENTS.

Upon the occurrence of any of the following events, a Participant's rights with respect to any Stock Right granted to him or her hereunder shall be adjusted as hereinafter provided, unless otherwise specifically provided in a Participant's Agreement:

(a) Stock Dividends and Stock Splits. If (i) the shares of Common Stock shall be subdivided or combined into a greater or smaller number of shares or if the Company shall issue any shares of Common Stock as a stock dividend on its outstanding Common Stock, or (ii) additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Common Stock, each Stock Right and the number of shares of Common Stock deliverable thereunder shall be appropriately increased or decreased proportionately, and appropriate adjustments shall be made including, to the exercise, base or purchase price per share, to reflect such events. The number of Shares subject to the limitations in Paragraph 3(a) shall also be proportionately adjusted upon the occurrence of such events.

(b) Corporate Transactions. If the Company is to be consolidated with or acquired by another entity in a merger, consolidation, sale of all or substantially all of the Company's assets or the acquisition of all of the outstanding voting stock of the Company in a single transaction or a series of related transactions by a single entity other than a transaction to merely change the state of incorporation (a "Corporate Transaction"), the Administrator or the board of directors of any entity assuming the obligations of the Company hereunder (the "Successor Board"), shall, as to outstanding Options, either (i) make appropriate provision for the continuation of such Options by substituting on an equitable basis for the Shares then subject to such Options either the consideration payable with respect to the outstanding shares of Common Stock in connection with the Corporate Transaction or securities of any successor or acquiring entity; or (ii) upon written notice to the Participants, provide that such Options must be exercised (either (A) to the extent then exercisable or, (B) at the discretion of the Administrator, any such Options being made partially or fully exercisable for purposes of this Subparagraph), within a specified number of days of the date of such notice, at the end of which period such Options which have not been exercised shall terminate; or (iii) terminate such Options in exchange for payment of an amount equal to the consideration payable upon consummation of such Corporate Transaction to a holder of the number of shares of Common Stock into which such Option would have been exercisable (either (A) to the extent then exercisable or, (B) at the discretion of the Administrator, any such Options being made partially or fully exercisable for purposes of this Subparagraph) less the aggregate exercise price thereof. For purposes of determining the payments to be made pursuant to Subclause (iii) above, in the case of a Corporate Transaction the consideration for which, in whole or in part, is other than cash, the consideration other than cash shall be valued at the fair value thereof as determined in good faith by the Board of Directors.

With respect to outstanding Stock Grants, the Administrator or the Successor Board, shall make appropriate provision for the continuation of such Stock Grants on the same terms and conditions by substituting on an equitable basis for the Shares then subject to such Stock Grants either the consideration payable with respect to the outstanding Shares of Common Stock in connection with the Corporate Transaction or securities of any successor or acquiring entity. In lieu of the foregoing, in connection with any Corporate Transaction, the Administrator may provide that, upon consummation of the Corporate Transaction, each outstanding Stock Grant shall be terminated in exchange for payment of an amount equal to the consideration payable upon consummation of such Corporate Transaction to a holder of the number of shares of Common Stock comprising such Stock Grant (to the extent such Stock Grant is no longer subject to any forfeiture or repurchase rights then in effect or, at the discretion of the Administrator, all forfeiture and repurchase rights being waived upon such Corporate Transaction). For purposes of determining such payments, in the case of a Corporate Transaction the consideration for which, in whole or in part, is other than cash, the consideration other than cash shall be valued at the fair value thereof as determined in good faith by the Board of Directors.

In taking any of the actions permitted under this Paragraph 24(b), the Administrator shall not be obligated by the Plan to treat all Stock Rights, all Stock Rights held by a Participant, or all Stock Rights of the same type, identically.

(c) Recapitalization or Reorganization. In the event of a recapitalization or reorganization of the Company other than a Corporate Transaction pursuant to which securities of the Company or of another corporation are issued with respect to the outstanding shares of Common Stock, a Participant upon exercising an Option or accepting a Stock Grant after the recapitalization or reorganization shall be entitled to receive for the price paid upon such exercise or acceptance if any, the number of replacement securities which would have been received if such Option had been exercised or Stock Grant accepted prior to such recapitalization or reorganization.

(d) Adjustments to Stock-Based Awards. Upon the happening of any of the events described in Subparagraphs (a), (b) or (c) above, any outstanding Stock-Based Award shall be appropriately adjusted to reflect the events described in such Subparagraphs. The Administrator or the Successor Board shall determine the specific adjustments to be made under this Paragraph 24, including, but not limited to the effect of any Corporate Transaction and, subject to Paragraph 4, its determination shall be conclusive.

(e) Modification of Options. Notwithstanding the foregoing, any adjustments made pursuant to Subparagraph (a), (b) or (c) above with respect to Options shall be made only after the Administrator determines whether such adjustments would (i) constitute a “modification” of any ISOs (as that term is defined in Section 424(h) of the Code) or (ii) cause any adverse tax consequences for the holders of Options, including, but not limited to, pursuant to Section 409A of the Code. If the Administrator determines that such adjustments made with respect to Options would constitute a modification or other adverse tax consequence, it may in its discretion refrain from making such adjustments, unless the holder of an Option specifically agrees in writing that such adjustment be made and such writing indicates that the holder has full knowledge of the consequences of such “modification” on his or her income tax treatment with respect to the Option. This paragraph shall not apply to the acceleration of the vesting of any ISO that would cause any portion of the ISO to violate the annual vesting limitation contained in Section 422(d) of the Code, as described in Paragraph 6(b)(iv).

25. ISSUANCES OF SECURITIES.

Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of shares subject to Stock Rights. Except as expressly provided herein, no adjustments shall be made for dividends paid in cash or in property (including without limitation, securities) of the Company prior to any issuance of Shares pursuant to a Stock Right.

26. FRACTIONAL SHARES.

No fractional shares shall be issued under the Plan and the person exercising a Stock Right shall receive from the Company cash in lieu of such fractional shares equal to the Fair Market Value thereof.

27. WITHHOLDING.

In the event that any federal, state, or local income taxes, employment taxes, Federal Insurance Contributions Act withholdings or other amounts are required by applicable law or governmental regulation to be withheld from the Participant's salary, wages or other remuneration in connection with the issuance of a Stock Right or Shares under the Plan or for any other reason required by law, the Company may withhold from the Participant's compensation, if any, or may require that the Participant advance in cash to the Company, or to any Affiliate of the Company which employs or employed the Participant, the statutory minimum amount of such withholdings unless a different withholding arrangement, including the use of shares of the Company's Common Stock or a promissory note, is authorized by the Administrator (and permitted by law). For purposes hereof, the fair market value of the shares withheld for purposes of payroll withholding shall be determined in the manner set forth under the definition of Fair Market Value provided in Paragraph 1 above, as of the most recent practicable date prior to the date of exercise. If the Fair Market Value of the shares withheld is less than the amount of payroll withholdings required, the Participant may be required to advance the difference in cash to the Company or the Affiliate employer.

28. NOTICE TO COMPANY OF DISQUALIFYING DISPOSITION.

Each Employee who receives an ISO shall notify the Company in writing immediately after the Employee makes a Disqualifying Disposition of any Shares acquired pursuant to the exercise of an ISO. A Disqualifying Disposition is defined in Section 424(c) of the Code and includes any disposition (including any sale or gift) of such Shares before the later of (a) two years after the date the Employee was granted the ISO, or (b) one year after the date the Employee acquired Shares by exercising the ISO, except as otherwise provided in Section 424(c) of the Code. If the Employee has died before such Shares are sold, these holding period requirements do not apply and no Disqualifying Disposition can occur thereafter.

29. TERMINATION OF THE PLAN.

The Plan will terminate on March 28, 2028, the date which is ten years from the earlier of the date of its adoption by the Board of Directors and the date of its approval by the shareholders of the Company. The Plan may be terminated at an earlier date by vote of the shareholders or the Board of Directors of the Company; provided, however, that any such earlier termination shall not affect any Agreements executed prior to the effective date of such termination. Termination of the Plan shall not affect any Stock Rights theretofore granted.

30. AMENDMENT OF THE PLAN AND AGREEMENTS.

The Plan may be amended by the shareholders of the Company. The Plan may also be amended by the Administrator, including, without limitation, to the extent necessary to qualify any or all outstanding Stock Rights granted under the Plan or Stock Rights to be granted under the Plan for favorable federal income tax treatment as may be afforded ISOs under Section 422 of the Code (including deferral of taxation upon exercise), and to the extent necessary to qualify the Shares issuable under the Plan for listing on any national securities exchange or quotation in any national automated quotation system of securities dealers. Any amendment approved by the Administrator which the Administrator determines is of a scope that requires shareholder approval shall be subject to obtaining such shareholder approval. Any modification or amendment of the Plan shall not, without the consent of a Participant, adversely affect his or her rights under a Stock Right previously granted to him or her, unless such amendment is required by applicable law or necessary to preserve the economic value of such Stock Right. With the consent of the Participant affected, the Administrator may amend outstanding Agreements in a manner which may be adverse to the Participant but which is not inconsistent with the Plan. In the discretion of the Administrator, outstanding Agreements may be amended by the Administrator in a manner which is not adverse to the Participant. Nothing in this Paragraph 30 shall limit the Administrator's authority to take any action permitted pursuant to Paragraph 24.

31. EMPLOYMENT OR OTHER RELATIONSHIP.

Nothing in this Plan or any Agreement shall be deemed to prevent the Company or an Affiliate from terminating the employment, consultancy or director status of a Participant, nor to prevent a Participant from terminating his or her own employment, consultancy or director status or to give any Participant a right to be retained in employment or other service by the Company or any Affiliate for any period of time.

32. GOVERNING LAW.

This Plan shall be construed and enforced in accordance with the law of the State of Delaware.

**** Adopted March 28, 2018 ****

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated March 24, 2023, with respect to the consolidated financial statements of Diffusion Pharmaceuticals Inc., included herein and to the reference to our firm under the heading “Experts” in the prospectus.

/s/ KPMG LLP

McLean, VA
May 8, 2023

Consent of Independent Registered Public Accounting Firm

We consent to the use in this Registration Statement on Form S-4 of Diffusion Pharmaceuticals Inc. of our report dated May 10, 2023, relating to the financial statements of EIP Pharma, Inc., appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference of our firm under the heading “Experts” in such Registration Statement.

/s/ RSM US LLP

Boston, Massachusetts
May 10, 2023

DIRECTOR CONSENT

I hereby consent to serve as a director of Diffusion Pharmaceuticals Inc. (the "Company"), if elected as such, and to be named as a nominee or potential nominee for director of the Company in any registration statement filed by the Company under the Securities Act of 1933, as amended, including all amendments and post-effective amendments or supplements thereto and any prospectus and/or proxy statement contained therein.

/s/ John Alam, M.D.

Name: John Alam, M.D.

Date: May 10, 2023

DIRECTOR CONSENT

I hereby consent to serve as a director of Diffusion Pharmaceuticals Inc. (the "Company"), if elected as such, and to be named as a nominee or potential nominee for director of the Company in any registration statement filed by the Company under the Securities Act of 1933, as amended, including all amendments and post-effective amendments or supplements thereto and any prospectus and/or proxy statement contained therein.

/s/ Sylvie Grégoire, PharmD.

Name: Sylvie Grégoire PharmD.

Date: May 10, 2023

DIRECTOR CONSENT

I hereby consent to serve as a director of Diffusion Pharmaceuticals Inc. (the "Company"), if elected as such, and to be named as a nominee or potential nominee for director of the Company in any registration statement filed by the Company under the Securities Act of 1933, as amended, including all amendments and post-effective amendments or supplements thereto and any prospectus and/or proxy statement contained therein.

/s/ Jeff Poulton

Name: Jeff Poulton

Date: May 10, 2023

DIRECTOR CONSENT

I hereby consent to serve as a director of Diffusion Pharmaceuticals Inc. (the "Company"), if elected as such, and to be named as a nominee or potential nominee for director of the Company in any registration statement filed by the Company under the Securities Act of 1933, as amended, including all amendments and post-effective amendments or supplements thereto and any prospectus and/or proxy statement contained therein.

/s/ Marwan Sabbagh, M.D.

Name: Marwan Sabbagh, M.D.

Date: May 10, 2023

DIRECTOR CONSENT

I hereby consent to serve as a director of Diffusion Pharmaceuticals Inc. (the "Company"), if elected as such, and to be named as a nominee or potential nominee for director of the Company in any registration statement filed by the Company under the Securities Act of 1933, as amended, including all amendments and post-effective amendments or supplements thereto and any prospectus and/or proxy statement contained therein.

/s/ Frank Zavrl

Name: Frank Zavrl

Date: May 10, 2023



Canaccord Genuity LLC
535 Madison Avenue
New York, NY 10022

T1: 1.212.389.8000
cgf.com

Consent of Canaccord Genuity LLC

Board of Directors
Diffusion Pharmaceuticals Inc.
300 East Main Street, Suite 201
Charlottesville, VA 22902

We hereby consent to the inclusion of our opinion letter, dated March 29, 2023, to the Board of Directors of Diffusion Pharmaceuticals Inc. (“Diffusion”) as *Annex C* to, and reference thereto under the headings “Prospectus Summary—Reasons for the Merger,” “Prospectus Summary—Opinion of Diffusion’s Financial Advisor,” “Prospectus Summary—Summary of Risk Factors,” “Risk Factors,” “The Merger” (introductory paragraphs), “The Merger—Background of the Merger,” “The Merger—Diffusion Reasons for the Merger” “The Merger—Opinion of Diffusion’s Financial Advisor,” and “The Merger—Certain Unaudited Long-Range Financial Projections of EIP’s Business” in, the proxy statement/prospectus/information statement relating to the proposed merger involving Diffusion and EIP Pharma, Inc., which proxy statement/prospectus/information statement forms a part of the Registration Statement on Form S-4 being filed by Diffusion with the Securities and Exchange Commission (the “SEC”) on the date hereof.

By giving such consent, we do not thereby admit that we are experts with respect to any part of such Registration Statement within the meaning of the term “expert” as used in, or that we come within the category of persons whose consent is required under, the Securities Act of 1933, as amended, or the rules and regulations of the SEC promulgated thereunder.

Very truly yours,

/s/ Canaccord Genuity LLC
Canaccord Genuity LLC

May 10, 2023

Calculation of Filing Fee Table

Form S-4
(Form Type)DIFFUSION PHARMACEUTICALS INC.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees to Be Paid	Equity	Common Stock, \$0.001 par value per share	Other	7,507,236 ⁽¹⁾	—	\$12,879.12 ⁽²⁾	\$0.00011020	\$1.42				
Fees Previously Paid	—	—	—	—	—	—	—	—				
Carry Forward Securities												
Carry Forward Securities	—	—	—	—	—	—	—	—	—	—	—	—
	Total Offering Amounts					\$12,879.12 ⁽²⁾	—	\$1.42	—	—	—	—
	Total Fees Previously Paid							—				
	Total Fee Offsets							—				
	Net Fee Due							\$1.42				

(1)Relates to common stock (“Diffusion Common Stock”), \$0.001 par value per share, of Diffusion Pharmaceuticals Inc., a Delaware corporation (“Diffusion”), issuable to holders of common stock (“EIP Common Stock”), \$0.001 par value per share of EIP Pharma, Inc., a Delaware corporation (“EIP”), in the proposed merger of Dawn Merger Sub Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Diffusion, with and into EIP, with EIP continuing as a wholly-owned subsidiary of Diffusion and the surviving corporation of the merger, including shares of Diffusion Common Stock issuable in respect of EIP’s convertible notes (each, an “EIP Convertible Note”) and each of EIP’s Series A-1 preferred stock, par value \$0.001, EIP’s Series A-2 preferred stock, par value \$0.001, and EIP’s Series B preferred stock, par value \$0.001, all of which will be converted into shares of common stock of EIP immediately prior to the effective time of the merger. The amount of Diffusion Common Stock to be registered reflects the maximum number of shares of Diffusion Common Stock that are expected to be issued in connection with the merger, without taking into account the effect of any reverse stock split of the Diffusion Common Stock, assuming a pre-split exchange ratio of 0.1943, which exchange ratio was estimated based upon (i) the parties respective capitalizations as of the date of the Merger Agreement, (ii) the closing price of the Diffusion Common Stock the preceding day, and (iii) an assumed EIP Convertible Note conversion price of \$3.00. Pursuant to Rule 416 under the Securities Act of 1933, as amended, this registration statement also covers an indeterminate number of additional shares of Diffusion Common Stock as may be issuable as a result of stock splits, stock dividends or the like.

(2)Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(f)(2) of the Securities Act of 1933, as amended. EIP is a private company, no market exists for its securities, and EIP has an accumulated capital deficit. Therefore, the proposed maximum aggregate offering price for the shares expected to be issued pursuant to the merger is one-third of the aggregate par value of the EIP securities expected to be exchanged in the merger.