UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-37942

CervoMed Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	30-0645032
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

20 Park Plaza, Suite 424 Boston, Massachusetts	**02216**
(Address of Principal Executive Offices)	(Zip Code)

(617) 744-4400
(Registrant's Telephone Number, Including Area Code)

Not applicable
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CRVO	The NASDAQ Capital Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	☒	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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
☐ Yes ☒ No

There were 5,674,520 shares of common stock, par value $0.001 per share of CervoMed Inc. issued and outstanding as of November 9, 2023.

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Explanatory Note Regarding Company References and Other Defined Terms

As previously disclosed in our Current Report on Form 8-K filed on August 17, 2023 with the SEC, on August 16, 2023, the Delaware corporation formerly known as "Diffusion Pharmaceuticals Inc." completed the previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger, dated March 30, 2023 (the "Merger Agreement") by and among Diffusion Pharmacueticals Inc. ("Diffusion"), Dawn Merger Inc., a wholly-owned subsidiary of Diffusion ("Merger Sub") and EIP Pharmaceuticals, Inc. ("EIP "), pursuant to which Merger Sub merged with and into EIP, with EIP surviving the Merger a wholly-owned subsidiary of Diffusion (the "Merger"). Additionally, on August 16, 2023, Diffusion changed its name from "Diffusion Pharmaceuticals Inc." to "CervoMed Inc."

Prior to the effective time of the Merger, on August 16, 2023, in connection with the transactions contemplated by the Merger Agreement, Diffusion effected a reverse stock split of the Company's common stock, par value $0.001 per share ("common stock"), at a ratio of 1-for-1.5 (the "Reverse Stock Split"). At the effective time of the Merger, each outstanding share of EIP capital stock was converted into the right to receive 0.1151 shares of Company common stock.

For accounting purposes, the Merger is treated as a reverse recapitalization under US GAAP and EIP Pharma, Inc. is considered the accounting acquirer. Accordingly, EIP's historical results of operations are deemed the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements. Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by EIP.

Accordingly, unless the context otherwise requires, all references in this Quarterly Report to (i) "CervoMed," the "Company," "we," "our," or "us," refer to the business of EIP for all dates and periods prior to August 16, 2023 and to the business of CervoMed for all dates and periods subsequent to (and including) August 16, 2023 and (ii) "common stock" refer to the common stock, par value $0.001 per share, of the Company, after giving effect to the Reverse Stock Split. Historical share and per share figures of EIP have been retroactively restated based upon the exchange ratio of 0.1151.

We have also used several other defined terms in this Quarterly Report, many of which are explained or defined below:

Term	Definition
2015 Equity Plan	CervoMed Inc. 2015 Equity Incentive Plan, as amended
2018 Plan	CervoMed Inc. 2018 Employee, Director and Consultant Equity Incentive Plan, as amended
2020 Notes	the previously outstanding convertible promissory notes of EIP, dated as of December 4, 2020, as amended
2021 Notes	the previously outstanding convertible promissory notes of EIP, dated as of December 10, 2021, as amended
2023 Notes Amendment	the amendments to the 2020 Notes and 2021 Notes entered into in June 2023
401(k) Plan	CervoMed Inc. 401(k) Defined Contribution Plan
AD	Alzheimer's Disease
Annual Report	our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 24, 2023
ACA	Affordable Care Act and the Healthcare and Education Reconciliation Act
AIA	America Invents Act
AMP	average manufacturer price
API	active pharmaceutical ingredient
ASC	Accounting Standard Codification of the FASB
ASU	Accounting Standards Update
Bayh-Doyle Act	Bayh-Dole Act of 1980
BFC	basal forebrain cholinergic
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CDR-SB	Clinical Dementia Rating Sum of Boxes test
cGMP	current good manufacturing practices
CMO	contract manufacturing organization
CMS	the U.S. Centers for Medicine & Medicaid Services
Convertible Notes	collectively, the 2020 Notes and the 2021 Notes
CNS	central nervous system
Code	the U.S. Internal Revenue Code of 1986, as amended
CRO	contract research organization
DLB	Dementia with Lewy Bodies
DNP	the FDA's Division of Neurology Products
Effective Time	the effective time of the Merger on August 16, 2023
EIP Common Stock	the common stock, par value $0.001, of EIP issued and outstanding prior to the Merger
EMA	European Medicines Agency
EOAD	Early Onset Alzheimer's Disease
Exchange Act	Securities Exchange Act of 1934, as amended
FASB	Financial Accounting Standards Board
FCPA	the Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
G&A	general and administrative
GDPR	EU General Data Protection Regulation
HIPAA	the Health Insurance Portability and Accountability of Act of 1996
IND	investigational new drug application
IRA	Inflation Reduction Act of 2022
License Agreement	the Option and License Agreement, dated as of August 27, 2012, by and between EIP Pharma LLC and Vertex, as amended
NASDAQ	Nasdaq Stock Market, LLC
NDA	new drug application
NIA	the National Institute on Aging of the National Institutes of Health
NOL	net operating loss

p38α	p38 mitogen-activated protein kinase alpha
PBM	pharmacy benefit mangers
POC	proof-of-concept
Quarterly Report	this Quarterly Report on Form 10-Q
R&D	research and development
Regulation S-K	Regulation S-K promulgated under the Securities Act of 1933, as amended
REMS	Risk Evaluation and Mitigation Strategy
Reverse recapitalization	Accounting treatment of the Merger
ROU	right-of-use
SAE	serious adverse events
SEC	U.S. Securities and Exchange Commission
Section 382	Section 382 of the Code
TCJA	Tax Cuts and Jobs Act of 2017
TID	three times daily
TSC	trans sodium crocetinate
TUG	Timed Up and Go test
U.S.	United States
US GAAP	U.S. generally accepted accounting principles
USPTO	U.S. Patent and Trademark Office
Vertex	Vertex Pharmaceuticals Incorporated

Note Regarding Forward-Looking Statements

This Quarterly Report (including, for purposes of this Note Regarding Forward-Looking Statements, any information or documents incorporated herein by reference) includes express and implied forward-looking statements. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition, liquidity, and prospects may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition, liquidity, and prospects are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of actual results or reflect unanticipated developments in future periods.

Forward-looking statements appear in a number of places throughout this Quarterly Report. We may, in some cases, use terms such as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements also include statements regarding our intentions, beliefs, projections, outlook, analyses or expectations concerning, among other things:

- our cash balances and our ability to obtain additional financing in the future and continue as a going concern;
- the success and timing of our ongoing Phase 2b clinical trial in patients with DLB and our other clinical and preclinical studies, including our ability to enroll subjects in our studies at anticipated rates and our ability to manufacture an adequate amount of drug supply for our studies;
- obtaining and maintaining intellectual property protection for our current or future product candidates and our proprietary technology;
- the performance of third parties, including contract research organizations, manufacturers, suppliers, and outside consultants, to whom we outsource certain operational, staff and other functions;
- our ability to obtain and maintain regulatory approval of our current or future product candidates and, if approved, our products, including the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our current or future product candidates and the outcomes of our research and development activities;
- our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- our future obligations under our License Agreement with Vertex;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the accuracy of our estimates of the size and characteristics of the potential markets for our current or future product candidates, the rate and degree of market acceptance of any of our current or future product candidates that may be approved in the future, and our ability to serve those markets;
- the success of products that are or may become available which also target the potential markets for our current or future product candidates;
- our ability to operate our business without infringing the intellectual property rights of others and the potential for others to infringe upon our intellectual property rights;
- any significant breakdown, infiltration, or interruption of our information technology systems and infrastructure;
- our ability to remediate our previously disclosed material weaknesses in our internal controls over financial reporting in a timely manner;
- our ability to successfully integrate the historical businesses of EIP and Diffusion and realize the anticipated benefits of the Merger;
- recently enacted and future legislation related to the healthcare system;
- other regulatory developments in the U.S., European Union, and other foreign jurisdictions;
- our ability to satisfy the continued listing requirements of the NASDAQ Capital Market or any other exchange on which our securities may trade in the future;
- uncertainties related to general economic, political, business, industry, and market conditions, including the continued availability of funding for the NIA to support disbursements under our previously received grant and

- other risks and uncertainties, including those discussed under the heading "Risk Factors" herein and in our other public filings.

As a result of these and other factors, known and unknown, actual results could differ materially from our intentions, beliefs, projections, outlook, analyses, or expectations expressed in any forward-looking statements in this Quarterly Report. Accordingly, we cannot assure you that the forward-looking statements contained in this Quarterly Report will prove to be accurate or that any such inaccuracy will not be material. You should also understand that it is not possible to predict or identify all such factors, and you should not consider any such list to be a complete set of all potential risks or uncertainties. In light of the foregoing and the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Any forward-looking statements that we make in this Quarterly Report speak only as of the date of such statement, and, except as required by applicable law or by the rules and regulations of the SEC, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. Comparisons of current and any prior period results are not intended to express any ongoing or future trends or indications of future performance, unless explicitly expressed as such, and should only be viewed as historical data.

Note Regarding Trademarks, Trade Names and Service Marks

This Quarterly Report includes trademarks, trade names, and service marks owned by us or other companies. All trademarks, service marks and trade names included in this Quarterly Report are the property of their respective owners. To the extent any such terms appear without the trade name, trademark, or service mark notice, such presentation is for convenience only and should not be construed as being used in a descriptive or generic sense.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CervoMed Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 10,424,675	$ 4,093,579
Prepaid expenses and other current assets	1,418,745	64,127
Total current assets	11,843,420	4,157,706
Other assets	194,443	-
Total assets	$ 12,037,863	$ 4,157,706
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 533,790	$ 97,302
Deferred grant revenue	547,051	-
Accrued expenses and other current liabilities	1,382,822	644,252
Convertible Notes	-	12,414,000
Total liabilities	2,463,663	13,155,554
Commitments and contingencies (Note 10)		
Convertible preferred stock:		
Series preferred stock $0.001 par value; 30,000,000 shares authorized 0 shares issued and outstanding at September 30, 2023 and December 31, 2022	-	-
Series A-1 preferred stock $0.001 par value; 1,960,600 shares authorized; 0 and 1,960,600 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	246,849
Series A-2 preferred stock, $0.001 par value; 335,711 shares authorized; 0 and 335,711 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	4,173,267
Series B preferred stock, $0.001 par value; 1,034,890 shares authorized; 0 and 1,034,890 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	19,867,095
Total convertible preferred stock	-	24,287,211
Stockholders' equity (deficit):		
Common stock, $0.001 par value: 1,000,000,000 shares authorized, 5,674,354 and 518,140 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	5,674	518
Additional paid-in capital	61,646,917	18,983,339
Accumulated deficit	(52,078,391)	(52,268,916)
Total stockholders' equity (deficit)	$ 9,574,200	(33,285,059)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 12,037,863	$ 4,157,706

See accompanying notes to unaudited condensed consolidated interim financial statements

CervoMed Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Grant revenue	$ 1,526,482	$ -	$ 4,654,294	$ -
Operating expenses:				
Research and development	1,791,487	330,543	5,583,149	955,784
General and administrative	2,410,124	573,511	4,403,590	1,580,927
Total operating expenses	4,201,611	904,054	9,986,739	2,536,711
Loss from operations	(2,675,129)	(904,054)	(5,332,445)	(2,536,711)
Other income (expense):				
Other income (expense)	4,777,824	(88)	5,422,192	(1,769,093)
Interest income	47,667	21,519	100,778	30,157
Total other income (expense)	4,825,491	21,431	5,522,970	(1,738,936)
Net income (loss)	$ 2,150,362	$ (882,623)	$ 190,525	$ (4,275,647)
Per share information:				
Net income (loss) per share of common stock - basic	$ 0.65	$ (1.70)	$ 0.13	$ (8.25)
Weighted average shares outstanding - basic	3,308,302	518,140	1,458,415	518,140
Net income (loss) per share of common stock - diluted	$ (0.70)	$ (1.70)	$ (2.37)	$ (8.25)
Weighted average shares outstanding - diluted	3,766,700	518,140	2,209,407	518,140

See accompanying notes to unaudited condensed consolidated interim financial statements

CervoMed Inc.
Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit
(unaudited)

Three Month Period Ended September 30, 2023

	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at June 30, 2023	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 19,116,831	$ (54,228,753)	$ (35,111,404)
Conversion of preferred stock to common stock	(1,960,600)	(246,849)	(335,711)	(4,173,267)	(1,034,890)	(19,867,095)	2,936,566	2,937	24,284,274	-	24,287,211
Issuance of common stock upon settlement of convertible notes	-	-	-	-	-	-	795,905	796	6,988,953	-	6,989,749
Issuance of common stock to Diffusion stockholders in reverse recapitalization, net of issuance costs	-	-	-	-	-	-	1,360,244	1,360	10,337,754	-	10,339,114
Sale of common stock	-	-	-	-	-	-	63,422	63	809,937	-	810,000
Stock-based compensation expense, including vesting of RSUs	-	-	-	-	-	-	77	-	109,168	-	109,168
Net income	-	-	-	-	-	-	-	-	-	2,150,362	2,150,362
Balance at September 30, 2023	-	$ -	-	$ -	-	$ -	5,674,354	$ 5,674	$ 61,646,917	$ (52,078,391)	$ 9,574,200

Nine Month Period Ended September 30, 2023

	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at January 1, 2023	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 18,983,339	$ (52,268,916)	$ (33,285,059)
Conversion of convertible preferred stock to common stock	(1,960,600)	(246,849)	(335,711)	(4,173,267)	(1,034,890)	(19,867,095)	2,936,566	2,937	24,284,274	-	24,287,211
Issuance of common stock upon settlement of convertible notes	-	-	-	-	-	-	795,905	796	6,988,953	-	6,989,749
Issuance of common stock to Diffusion stockholders in reverse recapitalization, net of issuance costs	-	-	-	-	-	-	1,360,244	1,360	10,337,754	-	10,339,114
Sale of common stock	-	-	-	-	-	-	63,422	63	809,937	-	810,000
Stock-based compensation expense, including vesting of RSUs	-	-	-	-	-	-	77	-	242,660	-	242,660
Net income	-	-	-	-	-	-	-	-	-	190,525	190,525
Balance at September 30, 2023	-	$ -	-	$ -	-	$ -	5,674,354	$ 5,674	$ 61,646,917	$ (52,078,391)	$ 9,574,200

Three Month Period Ended September 30, 2022

	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at June 30, 2022	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 18,819,968	$ (49,858,893)	$ (31,038,407)
Stock-based compensation expense	-	-	-	-	-	-	-	-	82,384	-	82,384
Net loss	-	-	-	-	-	-	-	-	-	(882,623)	(882,623)
Balance at September 30, 2022	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 18,902,352	$ (50,741,516)	$ (31,838,646)

Nine Month Period Ended September 30, 2022

	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2022	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 18,521,988	$ (46,465,869)	$ (27,943,363)
Stock-based compensation expense	-	-	-	-	-	-	-	-	252,847	-	252,847
Contributed capital in lieu of executive compensation	-	-	-	-	-	-	-	-	127,517	-	127,517
Net loss	-	-	-	-	-	-	-	-	-	(4,275,647)	(4,275,647)
Balance at September 30, 2022	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 18,902,352	$ (50,741,516)	$ (31,838,646)

See accompanying notes to unaudited condensed consolidated interim financial statements

CervoMed Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net income (loss)	$ 190,525	$ (4,275,647)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	242,660	252,847
Capital in lieu of executive compensation	-	127,516
Change in fair value of convertible debt	(5,424,251)	1,769,000
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(1,549,061)	111,496
Accounts payable	382,675	57,347
Accrued expenses and other liabilities	699,008	77,212
Deferred grant revenue	547,051	-
Net cash used in operating activities	(4,911,393)	(1,880,229)
Net assets assumed in connection with reverse recapitalization	11,887,757	-
Proceeds from sale of common stock	810,000	-
Payment of reverse recapitalization costs	(1,455,268)	-
Net cash provided by financing activities	11,242,489	-
Net increase (decrease) in cash and cash equivalents	6,331,096	(1,880,229)
Cash and cash equivalents at beginning of period	4,093,579	6,666,338
Cash and cash equivalents at end of period	$ 10,424,675	$ 4,786,109
Supplemental disclosure of non-cash financing activities:		
Conversion of Convertible Notes	$ 6,989,749	$ -
Conversion of convertible preferred stock	$ 24,287,211	$ -
Merger costs in accounts payable and accrued expenses	$ 93,375	$ -

See accompanying notes to unaudited condensed consolidated interim financial statements

CervoMed Inc.
Notes to Unaudited Condensed Consolidated Interim Financial Statements

1. The Company and Description of Business

The Company, a corporation organized under the laws of the state of Delaware and headquartered in Boston, Massachusetts, is a clinical-stage biotechnology company developing treatments for degenerative diseases of the brain. The Company is currently developing its product candidate neflamapimod, an investigational orally administered small molecule brain penetrant that inhibits p38α. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in DLB and certain other major neurological disorders, and is currently being evaluated in a Phase 2b study in patients with DLB.

On March 30, 2023, the Company, Merger Sub, and EIP entered into the Merger Agreement (Note 4), pursuant to which, at the Effective Time, Merger Sub merged with and into EIP, with EIP surviving the Merger as a wholly-owned subsidiary of the Company. In connection with the Merger, on August 16, 2023, the Company changed its corporate name from “Diffusion Pharmaceuticals Inc.” to “CervoMed Inc.”

On August 16, 2023, Diffusion approved a one-for-1.5 reverse stock split which was consummated for historical Diffusion shares in connection with the Merger. In addition, upon consummation of the Merger, all historical EIP shares were adjusted using an exchange ratio of .1151. All information in the accompanying unaudited condensed consolidated interim financial statements and notes thereto regarding share amounts of common stock, price per share of common stock and the conversion factor for preferred stock into common stock have been adjusted to reflect the application of the reverse stock split and the exchange ratio on a retroactive basis.

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 Convertible Notes (and excluding shares held as treasury stock by EIP, shares held or owned by the Company and any dissenting shares), converted into the right to receive, in the aggregate, 4,314,033 shares of the Company’s common stock and prefunded warrants to purchase 495,995, based on an exchange ratio of 0.1151.

2. Liquidity and Capital Resources

The Company has generated negative cash flows from operations and, as of September 30, 2023, had an accumulated deficit of approximately $52.1 million. In January 2023, the Company was awarded a $21.0 million grant from the NIA to support its ongoing Phase 2b study of neflamapimod in DLB, which is expected to be received over a three-year period. In July 2023, the Company sold common stock for proceeds of $0.8 million. In addition, the Company received $12.7 million in cash and cash equivalents through the reverse recapitalization.

Based on our current operating plan, we believe that the Company’s existing cash and cash equivalents on hand as of September 30, 2023, along with the remaining funds to be received from the NIA grant, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance of these unaudited condensed consolidated interim financial statements. 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 a 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.

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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 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.

The Company expects that its existing cash and cash equivalents as of September 30, 2023 will enable it to fund its operating expenses and capital expenditure requirements, including expected costs related to the ongoing Phase 2b trial for at least twelve months following the issuance of these condensed consolidated interim financial statements.

3. Summary of Significant Accounting Policies

Basis of presentation

The unaudited condensed consolidated interim financial statements have been prepared in conformity with US GAAP as defined by the FASB.

Unaudited condensed consolidated interim financial statements

The accompanying unaudited condensed consolidated interim financial statements have been prepared by the Company in accordance with US GAAP for interim information and pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in unaudited condensed consolidated interim financial statements prepared in accordance with US GAAP have been condensed or omitted pursuant to such rules and regulations. These unaudited condensed consolidated interim financial statements should be read in conjunction with the audited financial statements and related notes for the year ended December 31, 2022, which begin on page F-30 of the Difffusions Amended Registration Statement on Form S-4 as filed with the SEC on July 11, 2023.

The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the audited financial statements, and in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods. The results of operations for any interim period are not necessarily indicative of the results to be expected for the full fiscal year.

Consolidation

The unaudited condensed consolidated interim financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of unaudited condensed consolidated interim financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, grant revenue, 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, stock-based compensation expense, grant revenue, Convertible Notes, and 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 significantly from those estimates or assumptions.

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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 period ended September 30, 2023.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, accounts payable, previously outstanding 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 8. In connection with the consummation of the Merger (Note 4) on August 16, 2023, the Convertible Notes were converted into EIP Common Stock which was subsequently converted into the right to exchange such shares of EIP Common Stock for shares of the Company's common stock.

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.

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The following table presents the Company's assets that are measured at fair value on a recurring basis:

	September 30, 2023		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents (money market accounts)	$ 10,424,675	$ -	$ -
Total assets measured at fair value	$ 10,424,675	$ -	$ -

	December 31, 2022		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents (money market accounts)	$ 4,093,579	$ -	$ -
Total assets measured at fair value	$ 4,093,579	$ -	$ -
Liabilities			
Convertible Notes	$ -	$ -	$ 12,414,000
Total liabilities measured at fair value	$ -	$ -	$ 12,414,000

The following table presents a roll-forward of the fair value of the Convertible Notes (Note 9) for which fair value is determined by Level 3 inputs:

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Beginning balance	$ 12,414,000	$ 10,025,000
Fair value adjustment	(5,424,251)	2,389,000
Reclassification to additional paid in capital upon conversion	(6,989,749)	-
Ending balance	$ -	$ 12,414,000

	Three Months Ended	
	September 30, 2023	September 30, 2022
Beginning balance	$ 11,768,000	$ 12,414,000
Fair value adjustment	(4,778,251)	-
Reclassification to additional paid in capital upon conversion	(6,989,749)	-
Ending balance	$ -	$ 12,414,000

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs (Note 9). The Company's 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 nine months ended September 30, 2023 or in the year ended December 31, 2022.

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The fair value of the 2020 Notes and the 2021 Notes, and collectively the Convertible Notes (Note 9) as of December 31, 2022 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. This approach resulted in the classification of the 2020 Notes and the 2021 Notes as of December 31, 2022 as Level 3 of the fair value hierarchy. 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 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.

Leases

In February 2016, the FASB issued ASU No. 2016-02, “Leases”, which establishes a ROU model. 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 Statement of Operations as well as the reduction of the ROU 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.

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 ROU 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 will be recognized on the unaudited interim condensed consolidated balance sheet as ROU assets, lease liabilities current and lease liabilities non-current. Fixed rent payments 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.

Research and Development

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 makes 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.

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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 in the unaudited interim condensed consolidated statement of operations.

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 stock-based awards.

Expected Volatility—The Company has limited information on the volatility of its common stock as the shares were not actively traded on any public markets until recently. 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.

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Notes to Unaudited Condensed Consolidated Interim Financial Statements

Revenue Recognition

The Company generates revenue from government contracts that reimburse the Company for certain allowable costs for funded projects.

The Company recognizes funding received as grant revenue for the Company's grant from the NIA, rather than as a reduction of research and development expenses, because the Company is the principal in conducting the research and development activities and these contracts are central to its ongoing operations. Revenue is recognized as the qualifying expenses related to the contracts are incurred. Revenue recognized upon incurring qualifying expenses in advance of receipt of funding is recorded in the Company's unaudited interim condensed consolidated balance sheet as accounts receivable. Amounts received in advance of services rendered are recorded as deferred grant revenue. The related costs incurred by the Company are included in research and development expense in the Company's unaudited interim condensed consolidated statements of operations.

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 unaudited condensed consolidated interim 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, if any, 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 unaudited interim condensed consolidated balance sheet.

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Net Income (Loss) Per Share

Basic net income (loss) per share of common stock is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during each period. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, Convertible Notes (inclusive of change in fair value of Convertible Notes), stock options, and warrants, which would result in the issuance of incremental shares of common stock. For diluted net loss per share in periods where the Company has a net loss, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation. For the three and nine months ended September 30, 2023, the Company was in a net income position and calculated the diluted net income per share by dividing the Company's net income by the dilutive weighted average number of share outstanding during the periods, determined using the treasury stock method and the average stock price during the period. The pre-funded warrants to purchase common stock issued in connection with the Merger are included in the calculation of basic and diluted net loss per share as the exercise price of $0.001 per share is non-substantive and is virtually assured. The pre-funded warrants are more fully described in Note 11. A reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share calculations are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net income (loss)	$ 2,150,362	$ (882,623)	$ 190,525	$ (4,275,647)
Change in fair value of Convertible Notes	(4,778,251)	-	(5,424,251)	-
Adjusted net income (loss)	$ (2,627,889)	$ (882,623)	$ (5,233,726)	$ (4,275,647)
Denominator				
Weighted average shares outstanding, basic	3,308,302	518,140	1,458,415	518,140
Weighted average Convertible Notes before conversion	458,398	-	750,992	-
Weighted average shares outstanding, diluted	3,766,700	518,140	2,209,407	518,140
Net income (loss), basic	$ 0.65	$ (1.70)	$ 0.13	$ (8.25)
Net income (loss), dilutive	$ (0.70)	$ (1.70)	$ (2.37)	$ (8.25)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	Three and Nine Months Ended September 30,	
	2023	2022
Preferred Series A-1	-	1,960,600
Preferred Series A-2	-	335,711
Preferred Series B	-	1,034,890
Warrants	598,457	43,618
Stock options	329,340	141,831
Total	927,797	3,516,650

Segments

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a condensed consolidated basis for purposes of allocating resources.

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Recently Issued But Not Yet Adopted Accounting Pronouncements

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 US 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 adopted ASU No. 2016-13 on January 1, 2023 which did not have a material impact on the financial statements.

In January 2021, the FASB issued ASU No. 2021-01 "Reference Rate Reform (Topic 848): Scope" ("ASU 2021-01"), which was effective immediately and 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. Additionally, ASU 2022-06 "Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848" defers the sunset date of ASC 848 from December 31, 2022 to December 31, 2024. The new guidance is effective for fiscal years beginning after December 31, 2024. The Company does not currently believe that this transition from LIBOR will have a material impact on its financial statements.

4. Merger

On August 16, 2023, the Company completed the Merger of EIP and Merger Sub as discussed in Note 1. For financial reporting purposes, EIP was determined to be the accounting acquirer based upon the terms of the Merger and other factors, including: (i) EIP securityholders immediately prior to the Merger owning approximately 76% of the Company immediately following the Merger, (ii) EIP appointing the majority (five of seven) of the Company's board of directors immediately following the Merger and (iii) former EIP management holding the majority of key positions of management, including the Chief Executive Officer and Chairman of the Board of Directors positions, immediately following the Merger. The Merger was also accounted for as a reverse recapitalization under US GAAP because the primary assets of the Company immediately prior to the Merger were cash and cash equivalents. Accordingly, (i) for all periods prior to the Merger, EIP's historical financial statements and results of operations replace and are deemed to be the Company's financial statement and results of operations for such periods, (ii) the Merger was treated as the equivalent of EIP issuing shares of common stock to the holders of the Company's common stock immediately prior to the Merger as consideration to acquire the net assets of the Company, and (iii) the net assets of the Company as of immediately prior to the Merger were recorded at their acquisition-date fair value in the condensed consolidated financial statements of EIP. Immediately after the Merger, there were approximately 5,674,277 shares of the Company's common stock outstanding.

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The following table shows the net assets acquired in the Merger:

	August 16, 2023
Cash and cash equivalents	$ 12,705,140
Prepaid and other assets	406,488
Accounts payable and accrued expenses	(1,223,871)
Total net assets assumed	11,887,757
Minus: Transaction costs	(1,548,643)
Total net assets assumed minus transaction costs	$ 10,339,114

5. Significant Agreements and Contracts

Vertex Option and License Agreement

In August 2012, the Company entered the License Agreement, as amended, to acquire an exclusive license to develop and commercialize a drug candidate "VX-745" from Vertex. In August 2014, the Company exercised its option to acquire the license and paid an option fee of $100,000, which was expensed as incurred as a component of research and development expense.

The License Agreement granted the Company the exclusive worldwide use of VX-745 in the field of diagnosis, treatment and prevention of Alzheimer's disease and related central nervous system disorders in humans.

As part of the License Agreement, the Company is obligated to make certain payments totaling up to approximately $117.0 million upon achievement of certain regulatory and sales milestones, and royalties on net sales of products on indications covered by the License Agreement. 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, and 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 Company has made a total of $100,000 in payments to Vertex related to the License Agreement. No payments were made during the three and nine months ended September 30, 2023.

National Institute of Aging 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 expected to be received over a period of three years including $6.7 million in 2023, $8.1 million in 2024 and $6.2 million in 2025.

The total revenue recognized from the NIA grant was $1.6 million and $4.7 million for the three and nine months ended September 30, 2023. As of September 30, 2023, total cash funding of $5.2 million has been received from the NIA grant, resulting in approximately $15.8 million in funding remaining. Of the $5.2 million funding received to date, $0.5 million has been recorded as deferred revenue in the interim condensed consolidated balance sheet at September 30, 2023.

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6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2023	December 31, 2022
Prepaid clinical expenses	$ 670,851	$ -
Insurance	604,275	9,937
Rent	-	2,455
Other	143,619	51,735
Total	$ 1,418,745	$ 64,127

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Professional fees	$ 492,772	$ 206,675
Employee compensation costs	696,570	364,070
Clinical development costs	71,979	23,185
Other	121,501	50,322
Total	$ 1,382,822	$ 644,252

8. Line of Credit

The Company established a line of credit with a lender during the year ended December 31, 2020 in the amount of $2.5 million with a variable interest rate of 1.75% over the 30-day LIBOR (7.19% and 6.08% at September 30, 2023 and December 31, 2022, respectively). The line is secured by the personal assets of the Company's Chief Executive Officer and Chair of the Board.

No drawdowns were made, and no costs incurred related to the line of credit during the nine months ended September 30, 2023 nor the year ended December 31, 2022.

9. Convertible Notes

In December 2020, EIP issued the 2020 Notes to predominantly related party investors for proceeds of $5.1 million. In December 2021, EIP issued the 2021 Notes to predominantly related party investors for proceeds of $6.0 million. Upon issuance, the Company elected the fair value option for the Convertible 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 adjustments recognized in other income (expense) were $4.8 million and $0 million for the three months ended September 30, 2023 and 2022, respectively. The fair value adjustments recognized in other income (expense) were $5.4 million and $(1.8) million for the nine months ended September 30, 2023 and 2022, respectively.

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In June 2023, EIP entered into the 2023 Notes Amendment which amended the conversion price of the Convertible Notes to $1.47 per share of EIP Common Stock upon effectiveness of the Merger with the Company or a 30% conversion discount upon the occurrence of any other reverse merger. Further, the amendment provided that if the Merger with the Company resulted in a holder of these notes beneficially owning more than 9.99% of the outstanding voting stock of the Company, then, the holder of these notes shall be granted pre-funded warrants in lieu of the Company's common stock for the conversion of any principal and accrued but unpaid interest in excess of such threshold. The exercise price of one share of the Company's common stock under this pre-funded warrant is equal to $0.001 (Note 11).

The 2023 Notes Amendment qualified as a modification in accordance with FASB ASC 470 *Debt*, since there were no concessions granted and no substantive change to the fair value of the conversion option before and after the 2023 Amendment. There was no financial statement impact as a result of the 2023 Amendment other than the change in fair value of the Convertible Notes during the nine months ended September 30, 2023 and debt issuance costs of approximately $50,000 that was recorded to general and administrative expenses.

As a result of the Merger (Note 4), pursuant to the terms thereof, the Convertible Notes converted into shares of EIP Common Stock which were subsequently converted into the right to exchange such shares for 897,272 shares of the Company's common stock and, in certain cases, pre-funded warrants to purchase the Company's common stock. Accordingly, the Convertible Notes were adjusted to fair value prior to conversion by multiplying the trading price of the Company's common stock at the date of the Effective Time and the 795,905 common shares and 101,367 pre-funded warrants issued upon conversion. The Company recorded a gain on the fair value adjustment of the Convertible Notes of $4.8 million and $5.4 million for the three and nine months ended September 30, 2023 and recorded $7.0 million to additional paid in capital for the issuance of common stock upon settlement of the Convertible Notes.

10. Commitments and Contingencies

Operating Leases

The Company has a short-term agreement to utilize membership-based co-working space in Charlottesville, Virginia and a short-term lease for office space in Boston, Massachusetts. Rent expense related to the Company's short-term agreements was approximately $8,000 and $3,000 for the three months ended September 30, 2023 and 2022, respectively. Rent expense related to the Company's short-term agreements was approximately $23,000 and $38,000 for the nine months ended September 30, 2023 and 2022, respectively.

Research and Development Arrangements

In the course of normal business operations, the Company would enter into agreements with universities and 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 represented 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.

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Defined Contribution Retirement Plan

The Company has established its 401(k) Plan, which 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 $3,946 for the three and nine months ended September 30, 2023.

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 and, on October 6, 2023, the court entered an order further continuing the trial date to April 24, 2024.

The Company believes that is has meritorious defenses to the claims alleged in this matter 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 financial position, results of operations and cash flows.

11. Stockholders' Equity (Deficit) and Common Stock Warrants

On August 16, 2023 in connection with the closing of the Merger, the following is reflected on the condensed consolidated interim financial statements of convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2023: (i) the issuance of 795,905 shares of common stock and 101,367 pre-funded warrants upon the settlement of the Convertible Notes, (ii) the conversion of 3,331,201 shares of convertible preferred stock into 2,936,566 shares of common stock and 394,628 prefunded warrants, and (iii) the issuance of 1,360,244 shares of common stock to Diffusion stockholders as consideration for the Merger.

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In July 2023, EIP sold 63,422 shares of common stock at $12.78 per share (as adjusted for the Exchange Ratio) for net proceeds of approximately $0.8 million.

Warrants

As of September 30, 2023, the Company had the following warrants outstanding to acquire shares of its common stock:

	Warrants Outstanding	Exercise Price	Expiration Date
Historical Diffusion common stock warrants	58,844	$26.27-$459.06	May 2024 through February 2026
Historical EIP common stock warrants	43,618	$ 19.81	April 2028
Pre-funded warrants issued related to closing of reverse recapitalization	495,995	$ 0.001	None
	598,457		

Upon completion of the Merger, the Convertible Notes and outstanding shares of EIP preferred stock converted into shares of EIP Common Stock which were subsequently converted into the right to exchange such shares for shares of the Company's common stock or, in certain cases, pre-funded warrants to purchase the Company's common stock.

12. 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. As of September 30, 2023, there were 614 shares available for future issuance under the 2015 Equity Plan.

2018 Employee, Director and Consultant Equity Incentive Plan

On March 28, 2018, EIP adopted the 2018 Plan, which was assumed by the Company pursuant to and in accordance with the terms of the Merger Agreement. Under the 2018 Plan, 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 and subject to applicable SEC and NASDAQ rules and regulations. 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 September 30, 2023, there were no shares available for issuance.

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The Company recorded stock-based compensation expense in the following expense categories of its unaudited interim condensed consolidated statements of operations for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 30,737	$ 41,546	$ 101,885	$ 134,559
General and administrative	78,431	40,838	140,775	118,288
Total stock-based compensation expense	$ 109,168	$ 82,384	$ 242,660	$ 252,847

The following table summarizes the activity related to all stock option grants for the nine months ended September 30, 2023:

	Number of Options	Weighted average exercise price per share
Balance at January 1, 2023	114,516	$ 25.98
Options assumed in the Merger	52,574	$ 313.67
Granted	162,250	$ 5.33
Outstanding at September 30, 2023	329,340	$ 61.73
Exercisable at September 30, 2023	148,912	$ 111.77

The Black-Scholes option-pricing model was used to estimate the grant date fair value of each stock option grant at the time of grant using the following weighted-average assumptions:

	September 30,	
	2023	2022
Expected term (in years)	5.75	6.00
Risk-free interest rate	4.4%	1.9%
Expected volatility	81.7%	80.3%
Dividend yield	0.0%	0.0%

No options were exercised during the three or nine months ended September 30, 2023 and 2022. At September 30, 2023, there was $1.0 million of unrecognized compensation expense that will be recognized over a weighted-average period of 2.3 years.

13. Restatement of Previously Issued (Unaudited) Interim Financial Statements

While undergoing a review of its unaudited condensed consolidated interim financial statements as of September 30, 2023, the Company determined it had incorrectly expensed costs directly associated with the Merger during various periods in 2023. Fees such as accounting and legal related to the Merger should have been capitalized and net against proceeds of the Merger. This impacted previously reported amounts for deferred offering costs and general and administrative expense, among other line items in the unaudited condensed consolidated interim financial statements as of and for the three months ended March 31, 2023 and as of and for the six months ended June 30, 2023.

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The following tables set forth the effects of the error corrections on affected items within the Company's previously reported unaudited interim condensed consolidated balance sheet as of the periods indicated had the adjustments been made in the corresponding quarter:

	June 30, 2023		
	As reported	Adjusted	As restated
Deferred offering costs	$ -	$ 1,059,768	$ 1,059,768
Accumulated deficit	$ (55,288,521)	$ 1,059,768	$ (54,228,753)
Total assets	$ 2,304,448	$ 1,059,768	$ 3,364,216
Total liabilities, convertible preferred stock and stockholder's deficit	$ 2,304,448	$ 1,059,768	$ 3,364,216
Total stockholders' deficit	$ (36,171,172)	$ 1,059,768	$ (35,111,404)

	March 31, 2023		
	As reported	Adjusted	As restated
Deferred offering costs	$ -	$ 638,018	$ 638,018
Accumulated deficit	$ (53,441,270)	$ 638,018	$ (52,803,252)
Total assets	$ 3,305,477	$ 638,018	$ 3,943,495
Total liabilities, convertible preferred stock and stockholder's deficit	$ 3,305,477	$ 638,018	$ 3,943,495
Total stockholders' deficit	$ (34,386,173)	$ 638,018	$ (33,748,155)

The following tables set forth the effects of the error corrections on affected items within the Company's previously reported unaudited interim condensed statements of operations for the periods indicated had the adjustments been made in the corresponding quarters:

	Six Months Ended June 30, 2023		
	As reported	Adjusted	As restated
General and administrative expense	$ 3,053,234	$ (1,059,768)	$ 1,993,466
Total operating expenses	$ 6,844,896	$ (1,059,768)	$ 5,785,128
Loss from operations	$ (3,717,084)	$ 1,059,768	$ (2,657,316)
Net loss	$ (3,019,605)	$ 1,059,768	$ (1,959,837)
Net loss per share of common stock, basic and diluted	$ (0.67)	$ 0.23	$ (0.44)

	Three Months Ended March 31, 2023		
	As reported	Adjusted	As restated
General and administrative expense	$ 1,638,931	$ (638,018)	$ 1,000,913
Total operating expenses	$ 3,472,205	$ (638,018)	$ 2,834,187
Loss from operations	$ (2,064,337)	$ 638,018	$ (1,426,319)
Net loss	$ (1,172,354)	$ 638,018	$ (534,336)
Net loss per share of common stock, basic and diluted	$ (0.26)	$ 0.14	$ (0.12)

14. Subsequent Events

The Company has evaluated subsequent events through the filing of this Quarterly Report and determined that there have been no events that have occurred that would require adjustments to our disclosures in the condensed consolidated interim financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

You should read the following discussion of our financial condition and results of operations together with the unaudited condensed consolidated interim financial statements and the notes thereto included elsewhere in this Quarterly Report and the other financial information included herein. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under the heading "Note Regarding Forward-Looking Statements" included elsewhere in this Quarterly Report, under the heading "Part I — Item 1A. Risk Factors" in our Annual Report, under the heading "Risk Factors" in Exhibit 99.2 to our amended Current Report on Form 8-K filed with the SEC on September 29, 2023, and in our other public filings. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

We are a clinical-stage biotechnology company advancing CNS-focused therapeutics to benefit patients with a range of degenerative diseases of the brain. We are currently developing neflamapimod, an investigational orally administered small molecule brain penetrant that inhibits p38α. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in DLB and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with DLB.

There are currently no approved therapies in DLB and no disease-modifying drugs in Phase 3 clinical trials. We believe that we are a leader in the industry, as we are the only company of which we are aware with an asset that, in DLB, has shown statistically significant positive effects compared to placebo in a Phase 2a clinical trial and has initiated a 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, including DLB. Chronic activation of the enzyme p38α 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 p38α activity 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.

Our lead drug candidate, neflamapimod, is an oral therapy that penetrates the blood-brain barrier and inhibits activity of p38α 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 Phase 2 clinical data in AD that provides support by demonstrating blood-brain-barrier penetration, target (p38α) engagement, and identification of dose-response.

There are an estimated 700,000 individuals with DLB in each of the U.S. and the European Union. 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 CDR-SB test, p=0.023 vs. placebo) and motor function (evaluated by the TUG test, TUG p=0.044 vs. placebo). In secondary analysis, at highest dose (40mg 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.

The primary analysis of the Phase 2a DLB trial was published in *Nature Communications* and showed neflamapimod significantly improved dementia severity and motor function. A recent publication in the major clinical neurology journal, *Neurology*, extends the observations of the initial publication, describing the consistency and greater magnitude of clinical effect in observed patients without AD co-pathology, which we believe further strengthens the conclusions regarding the clinical effect in DLB demonstrated in Phase 2a. A subsequent publication in *Molecular Neurodegeneration* provides a combined evaluation of the findings in the *Neurology* and *Nature Communications* articles that makes the case for advancing neflamapimod as a treatment for DLB

Our next step in the clinical development of neflamapimod is the execution of our ongoing Phase 2b placebo-controlled clinical trial, named RewinD-LB, which is a double-blind, 16-week study in 160 patients with early stage DLB randomized 1:1 to 40mg neflamapimod or placebo TID. Patients in both the neflamapimod and placebo groups who complete the main, randomized, double-blinded, 16-week phase of the study will receive neflamapimod on an open label basis for an additional 32 weeks. Clinical sites are located in the US, the UK, and the Netherlands. Patients with Alzheimer's disease-related co-pathology, assessed by a blood biomarker (plasma ptau181), will be excluded.

The RewinD-LB trial is intended to confirm, and the design of the trial is based upon, learnings from the Phase 2a DLB trial. Key distinctions in the design of the RewinD-LB trial from the Phase 2a study include, (1) the use of one dosing regimen of neflamapimod (40mg capsules three-times-a-day, TID), based on the dose-response analysis of the study, and on observations in AD studies; (2) the choice of CDR-SB as the primary endpoint; and (3) the exclusion of patients with Alzheimer's related co-pathology, as evaluated by plasma levels of tau phosphorylated at position 181 (ptau181; to enrich for such patients, the global CDR score at entry will be limited to 0.5 or 1.0). With these modifications to the design from Phase 2a, sample size calculations (see below) indicate that the RewinD-LB Phase 2b study has greater than 95% statistical power (approaching 100%) to meet its primary objective of demonstrating improvement relative to placebo on change in CDR-SB over the course of the study.

We expect to complete enrollment in RewinD-LB during the first half of 2024 and then report initial results from the placebo-controlled portion of the study during the second half of 2024. The RewinD-LB study is funded by a $21 million grant from the NIA, which will be disbursed over the course of the study as costs are incurred. The results of these studies are intended to 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.

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 EOAD. The scientific rationale for evaluating neflamapimod to promote recovery after stroke is predicated on the 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.

In 2012, we entered into the 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 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.

Financial Summary

As of September 30, 2023, we had cash and cash equivalents of approximately $10.4 million. 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 historically incurred net losses in each year ended since inception, though not in the current three and nine months ended September 30, 2023. Our ability to generate product revenue will depend on the successful development and eventual commercialization of neflamapimod. Our net income was $2.2 million and $0.2 million for the three months and nine months ended September 30, 2023, respectively. As of September 30, 2023, we had an accumulated deficit of $52.1 million. We expect our expenses will increase in connection with our ongoing activities, as we:

- advance neflamapimod through clinical trials, including our ongoing Phase 2b trial for DLB, through to initiation of a Phase 3 trial in DLB;
- hire additional personnel;
- continue to 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.

Based on our current operating plan, we believe that our existing cash and cash equivalents on hand as of September 30, 2023, along with the remaining funds to be received from the NIA grant, will enable us to fund our operating expenses and capital expenditure requirements through at least twelve months through the issuance of these interim financial statements. However, we expect to incur substantial expenditures in the foreseeable future for the development of neflamapimod and will require additional financing to continue this development.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales and we do not expect to do so in the near future. As of September 30, 2023, total cash funding of $5.2 million was received by us from the NIA grant. The total revenue recognized from the NIA grant was $1.6 million and $4.7 million for the three and nine months ended September 30, 2023, respectively. The funding that has not been recognized as revenue, $0.5 million as of September 30, 2023, has been recorded as deferred revenue.

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 us 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 recently initiated 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 research and development (“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 and the change in fair value of the previously outstanding EIP Convertible Notes.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30			
	2023	**2022**	**$ Change**	**% Change**
Grant revenue	$ 1,526,482	$ -	$ 1,526,482	100%
Operating expenses:				
Research and development	1,791,487	330,543	1,460,944	442%
General and administrative	2,410,124	573,511	1,836,613	320%
Loss from operations	(2,675,129)	(904,054)	(1,771,075)	196%
Other income (expense):				
Other income (expense)	4,777,824	(88)	4,777,912	(a)
Interest income	47,667	21,519	26,148	122%
Total other income (expense)	4,825,491	21,431	4,804,060	(a)
Net income (loss)	$ 2,150,362	$ (882,623)	$ 3,032,985	-344%

(a) Percentage not meaningful

Grant Revenue

Grant revenue was $1.5 million for the three months ended September 30, 2023 which was a result of services performed during the three months ended September 30, 2023 related to the $21.0 million grant awarded to us by the NIA in January 2023 to support a Phase 2b study of neflamapimod in DLB. As the NIA grant was initially awarded in January 2023, there was no grant revenue in the corresponding three-month period in the prior year.

Research and Development Expenses

Research and development expenses were $1.8 million for the three months ended September 30, 2023, compared to $0.3 million for the three months ended September 30, 2022. The increase of $1.5 million was primarily due to our DLB Phase 2b trial beginning in the first quarter of 2023.

General and Administrative Expenses

General and administrative expenses were $2.4 million for the three months ended September 30, 2023, compared to $0.6 million for the three months ended September 30, 2022. The increase of $1.8 million was primarily due to higher professional fees related to public company costs, as well as increased headcount as a result of the Merger.

Other Income (Expense)

Other income (expense) was $4.8 million for the three months ended September 30, 2023, compared to $(88) for the three months ended September 30, 2022. The amount for the three months ended September 30, 2022 was driven by an increase in the estimated fair value of the Convertible Notes while the increase in the three months ended September 30, 2023 was driven by the stock price on the date of conversion as a result of the Merger.

Interest income

Interest income was $48 thousand for the three months ended September 30, 2023, compared to $22 thousand for the three months ended September 30, 2022. The increase of $26 thousand was primarily due to higher interest earned on cash equivalents.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30			
	2023	**2022**	**$ Change**	**% Change**
Grant revenue	$ 4,654,294	$ -	$ 4,654,294	100%
Operating expenses:				
Research and development	5,583,149	955,784	4,627,365	484%
General and administrative	4,403,590	1,580,927	2,822,663	179%
Loss from operations	(5,332,445)	(2,536,711)	(2,795,734)	110%
Other income (expense):				
Other income (expense)	5,422,192	(1,769,093)	7,191,285	-406%
Interest income	100,778	30,157	70,621	234%
Total other income (expense)	5,522,970	(1,738,936)	7,261,906	-418%
Net income (loss)	$ 190,525	$ (4,275,647)	$ 4,466,172	-104%

Grant Revenue

Grant revenue was $4.7 million for the nine months ended September 30, 2023 services performed during the nine months ended September 30, 2023 related to the as a result of a $21.0 million grant awarded to us by the NIA in January 2023 to support a Phase 2b study of neflamapimod in DLB. As the NIA grant was initially awarded in January 2023, there was no grant revenue in the corresponding nine-month period in the prior year.

Research and Development Expenses

Research and development expenses were $5.6 million for the nine months ended September 30, 2023, compared to $1.0 million for the nine months ended September 30, 2022. The increase of $4.6 million was primarily due to our DLB Phase 2b trial beginning in the first quarter of 2023.

General and Administrative Expenses

General and administrative expenses were $4.4 million for the nine months ended September 30, 2023, compared to $1.6 million for the nine months ended September 30, 2022. The increase of $2.8 million was primarily due to higher professional fees related to public company costs as well as increased headcount as a result of the Merger.

Other Income (Expense)

Other income (expense) was $5.4 million for the nine months ended September 30, 2023, compared to $(1.8) million for the nine months ended September 30, 2022. The amount for the nine months ended September 30, 2022 was driven by an increase in the estimated fair value of the Convertible Notes while the increase in the nine months ended September 30, 2023 was driven by the stock price on the date of conversion as a result of the Merger.

Interest income

Interest income was $0.1 million for the nine months ended September 30, 2023, compared to $30 thousand for the nine months ended September 30, 2022. The increase of $70 thousand was primarily due to higher interest earned on cash equivalents.

Liquidity and Capital Resources

From the date of our inception through September 30, 2023, our operations had primarily been financed through the issuance of common stock, convertible preferred stock and convertible debt financings. As of September 30, 2023, we had approximately $10.4 million of cash and cash equivalents. We have not generated positive cash flows from operations and as of September 30, 2023, we had an accumulated deficit of approximately $52.1 million. In January 2023, we were awarded a $21.0 million grant from the NIA to support the Phase 2b study of neflamapimod in DLB, which is expected to be received over a three-year period. As of September 30, 2023, total cash funding of $5.2 million had been received from the NIA grant.

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 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 issuance date of our financial statements for the period ended September 30, 2023, raise substantial doubt about our ability to continue as a going concern. However, based on our current operating plan, we believe that our existing cash and cash equivalents on hand as of September 30, 2023, along with the remaining funds to be received from the NIA grant, will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of these interim financial statements.

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, we expect to incur 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 as of September 30, 2023, along with the remaining funds to be received from the NIA grant, will enable us to fund our operating expenses and capital expenditure requirements to the end of 2024. 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 a 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 enrollment, progress, timing, costs and results of the 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 Early Onset Alzheimer's Disease;
- 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 operations as 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 could significantly alter 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

	Nine Months Ended September 30,	
	2023	**2022**
Net cash used in operating activities	$ (4,911,393)	$ (1,880,229)
Net cash provided by financing activities	11,242,489	-
Net increase (decrease) in cash and cash equivalents	$ 6,331,096	$ (1,880,229)

Net Cash Used in Operating Activities

For the nine months ended September 30, 2023, cash used in operating activities was $4.9 million. The net cash outflow from operations primarily resulted from net income of $0.2 million and change in fair value of convertible debt of $5.4 million, offset by a non-cash charge of $0.2 million for stock-based compensation and changes in operating assets and liabilities of $0.1 million.

For the nine months ended September 30, 2022, cash used in operating activities was $1.9 million. The net cash outflow from operations primarily resulted from net loss of $4.3 million, offset by a change in fair value of convertible debt of $1.8 million, a non-cash charge of $0.3 million for stock-based compensation, contributed capital in lieu of executive compensation of $0.1 million and a change in operating assets and liabilities of $0.2 million.

Net Cash Provided by Financing Activities

For the nine months ended September 30, 2023, net cash provided by financing activities was $11.2 million. The net cash provided by financing activities primarily resulted from the net assets assumed in connection with the reverse capitalization, offset by the payment of offering costs.

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 do 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 our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources. As a result, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in these arrangements.

Critical Accounting Polices 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 U.S. generally accepted accounting principles. 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 and as such, expected volatility is derived from the historical stock volatilities of comparable peer public companies within our 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 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.

In periods prior to the Merger, the grant date fair value of EIP Common Stock was typically determined by EIP's Board of Directors with the assistance of management and a third party valuation specialist. Following 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 each equity grant.

For additional information regarding stock-based compensation in periods following the Merger, see Note 12 to the unaudited condensed consolidated interim financial statements included elsewhere in this Quarterly Report.

Valuation of Convertible Notes

The fair value of the Convertible Notes as of December 31, 2022 were estimated as the combination of a zero-coupon bond and a call option. The combined values for each of the Convertible Notes as of December 31, 2022 were then weighted by the probability of completing a financing or reverse merger. This approach resulted in the classification of the Convertible Notes as of December 31, 2022 as Level 3 of the fair value hierarchy (see Note 9 to the unaudited financial statements included elsewhere in this Quarterly Report). 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%.

In connection with the closing of the Merger, all outstanding EIP Convertible Notes converted into shares of EIP Common Stock at the fixed conversion price of $1.47 per share of EIP Common Stock, which shares of EIP Common Stock were subsequently converted into the right to receive shares of CervoMed common stock (or pre-funded warrants in lieu thereof) upon closing of the Merger.

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 Quarterly Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, promulgated by the SEC under the U.S. Securities Act of 1933, as amended, we are not required to provide the information required by this Item 3.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15I and 15d-15(e) promulgated under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we are required to apply our judgment in evaluating the cost-benefit relationship of possible internal controls. Our management evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are ineffective due to the material weaknesses noted below in the subsequent paragraph.

Material Weaknesses in Internal Control over Financial Reporting

In connection with the review of the Company's condensed consolidated interim financial statements for the period ended September 30, 2023, material weaknesses in the Company's internal control over financial reporting were identified in relation to: (i) the recording of significant complex transactions and (ii) the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our condensed consolidated interim financial statements would not be prevented or detected on a timely basis. The identified material weaknesses, if not corrected, could result in a material misstatement to the combined company's condensed consolidated interim financial statements that may not be prevented or detected.

The material weaknesses will not be considered remediated until a remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and it has been concluded, through testing, that the newly implemented and enhanced controls are operating effectively. The Company currently expects to commence the remediation plan during the fourth quarter of 2023 by adding additional review procedures by qualified personnel over complex accounting matters. The Company cannot predict the success of such efforts or the outcome of its assessment of the remediation efforts. The Company's efforts may not remediate this material weakness in its internal control over financial reporting, or additional material weaknesses may be identified in the future.

Changes in Internal Control over Financial Reporting

On August 16, 2023, we completed the Merger with EIP and Merger Sub. For financial reporting purposes, EIP was determined to be the accounting acquirer and, accordingly, for all periods prior to the Merger, EIP's historical financial statements and results of operations replace and are deemed to be the Company's financial statement and results of operations for such periods. We are currently integrating the pre-Merger business of EIP into the Company's pre-established internal control framework, including internal controls and information systems. This work began upon completion of the Merger in August 2023 and will continue throughout calendar year 2023 and potentially beyond. While the Company was previously subject to the provisions of the Sarbanes-Oxley Act of 2002, as amended, whereas EIP, as a private, non-reporting operating company prior to the Merger, was not. Accordingly, we do not believe the Company has an appropriate structure for internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report due to the material weaknesses described above.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

For this item, please refer to *Note 10, Commitments and Contingencies* in the notes accompanying the unaudited interim condensed consolidated interim financial statements included in Part I, Item 1 of this Quarterly Report, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS.

Investing in our securities involves a high degree of risk. Set forth below are certain material risks and uncertainties known to us that could adversely affect our business, financial condition, or results of operations or could cause our actual results to differ materially from our expectations expressed in our filings with the SEC and other public statements. The occurrence of the events contemplated by one or more of the factors we describe below could cause the market price of our securities to decline, resulting in the loss of all or part of any investment in our common stock. Furthermore, other risks that are currently unknown to us or that we currently believe to be immaterial may also, nevertheless, adversely affect our business, financial condition, or results of operations in a way that is material.

You should carefully consider the risk factors set forth below as may updated by our subsequent filings under the Exchange Act together with all other information in our filings with the SEC, including the unaudited financial information included in Part 1, Item 1 of this Quarterly Report and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part 1, Item 2 of this Quarterly Report, before making any investment decisions. Furthermore, the risks and uncertainties described below and in the information mentioned above are not the only ones the Company faces. Additional risks and uncertainties not presently known to the Company or that we currently believe to be immaterial could, nevertheless, adversely affect the Company's business, operating results and financial condition, as well as adversely affect the value of an investment in the Company's securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.

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

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

The Company is a clinical stage company focused on developing treatments for degenerative diseases of the brain, and currently has no products that are approved for commercial sale, and it is possible it may never be able to develop a marketable product. To date, the Company has not generated any revenues from its lead product candidate, neflamapimod, or from any other product candidate. The Company cannot guarantee that neflamapimod, or any other product candidate that it may develop or acquire in the future, will ever become marketable products.

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, the Company must demonstrate that its drug satisfies rigorous standards of safety and efficacy for each of its intended uses. In order to compete effectively, the Company's drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. The Company may not achieve any of these objectives.

The Company initiated a Phase 2b randomized double-blind placebo-controlled clinical study of neflamapimod in subjects with DLB in the second quarter of 2023 and anticipates completing enrollment in the study in the first half of 2024. The Company 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 the Company will yield a drug candidate suitable for investigation through clinical trials. Even if the Company 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.

The Company is a clinical-stage biopharmaceutical company, and it has incurred significant losses since its inception. The Company expects its net losses to continue for the foreseeable future. The Company is not currently profitable and may never achieve or sustain profitability. The Company 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 September 30, 2023, it had an accumulated deficit of approximately $52.1 million (without giving effect to the Merger (as defined below)). The Company expects to incur net losses for the foreseeable future as it incurs significant clinical development costs related to the advancement of neflamapimod. The Company 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, the Company must succeed, either alone or in collaboration with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. The Company may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

The Company 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, the Company 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 the Company's future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenues. If the Company 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 the Company does achieve profitability, it may not be able to sustain it, which could materially and adversely affect its business.

The Company will require additional capital to fund its operations. If the Company 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.

The Company 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 recently initiated Phase 2b clinical trial of neflamapimod in DLB and costs associated with its license agreement with Vertex, under which the Company is obligated to make certain payments in connection with the achievement of specified events.

Until such time, if ever, that the Company 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 the Company's current operating plan, the Company believes that the Company's existing cash and cash equivalents and a grant from the NIA will enable the Company to fund its operating expenses and capital expenditure requirements for at least the next 12 months. The Company'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 the Company currently expects. For example, the Company's recently initiated Phase 2b trial for neflamapimod may be more expensive, time-consuming, or difficult to implement than the Company currently anticipates. Because the length of time and activities associated with the successful development of neflamapimod is highly uncertain, the Company 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.

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

- the enrollment, progress, timing, costs and results of the Company's recently initiated Phase 2b trial for neflamapimod in patients with DLB, as the Company 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;
- the Company's ability to reach certain milestone events set forth in its agreement with Vertex and the timing of such achievements, triggering the Company's obligation to make applicable payments;
- the hiring of additional clinical, scientific and operational personnel to pursue the Company's development plans, as well the increased costs of internal and external resources as to support the Company'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 the Company's patent claims and other intellectual property rights, including defending against any patent infringement actions brought by third parties against the Company;
- the Company's ability to establish collaborations with other parties on favorable terms, if at all; and
- the extent to which the Company may in-license or acquire other product candidates or technologies.

The Company 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 The Company on acceptable terms, or at all. The Company'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 the Company is unable to secure additional capital in sufficient amounts or on terms acceptable to the Company, it may have to delay, scale back or discontinue its development or commercialization activities for neflamapimod.

Further, to the extent that the 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 Company will be diluted. In addition, any debt financing may subject the 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 Company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the 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 Company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the Company or its stockholders.

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

The Company's recently initiated 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 the Company'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, including due to a government shutdown that prohibits the disbursal of such funds, or the Company fails to demonstrate such progress, the Company's ability to continue its clinical programs may be impaired and delayed, and the Company may otherwise need to seek additional financing.

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

In connection with the NIA grant, the Company may be subject to routine audits by certain government agencies. As part of an audit, these agencies may review the Company'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 the Company's expenditures are found to be unallowable or allocated improperly or if the Company 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 the Company's results of operations and financial condition and harm the Company'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 the Company's failure to receive additional NIA grants to fund future clinical trials.

The Company 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 the Company has limited financial resources, it intends to focus on developing neflamapimod and future product candidates for specific indications that the Company identifies as most likely to succeed, in terms of both regulatory approval and commercialization. As a result, the Company may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. The Company's resource allocation decisions may cause the Company 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 the Company 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 the Company to retain sole development and commercialization rights to such product candidate.

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

In August 2012, the Company entered into the License Agreement with Vertex, which the Company amended in April 2014 and November 2015. Pursuant to the terms of the License Agreement, the Company acquired an exclusive license to develop and commercialize neflamapimod for the diagnosis, treatment, and prevention of AD and other CNS disorders.

Under the License Agreement, the Company 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 License Agreement sets forth specific regulatory and product approval events and the related payments that the Company would be obligated to make to Vertex if and when such events occur.

The terms of the License Agreement also provide that the Company 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. The Company 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 the Company 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. The Company 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 the Company's development efforts, as well as its overall financial condition.

The Company has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of the Company's financial statements and have other adverse consequences. The Company may identify additional material weaknesses in its internal controls over financing reporting which it may not be able to remedy in a timely manner.

In connection with the audit of the Company's financial statements for the year ended December 31, 2022, material weaknesses in the Company's internal control over financial reporting were identified in connection with review of the condensed consolidated unaudited interim financial statements for the period ended September 30, 2023, it was determined that these material weaknesses had not yet been remediated. These material weaknesses relate to (i) the Company's recording of significant complex transactions, and (ii) the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. The identified material weaknesses, if not corrected, could result in a material misstatement to the Company's consolidated financial statements that may not be prevented or detected. Given that EIP operated as a private company prior to August 16, 2023, it may not have the necessary formalized processes to effectively implement review controls within its internal control over financial reporting.

The material weaknesses will not be considered remediated until a remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and it has been concluded, through testing, that the newly implemented and enhanced controls are operating effectively. The Company currently expects to commence the remediation plan during 2023 by adding additional review procedures by qualified personnel over complex accounting matters and expense accounts. The Company cannot predict the success of such efforts or the outcome of its assessment of the remediation efforts. The Company's efforts may not remediate this material weakness in its internal control over financial reporting, or additional material weaknesses may be identified in the future. In addition, the Company plans to adopt Diffusion Pharmaceutical Inc.'s financial reporting processes. A failure to appropriately integrate financial reporting processes between the two companies, and to implement and maintain effective internal control over financial reporting could result in errors in the Company's financial statements that could result in a restatement of the Company's financial statements and could cause the Company to fail to meet our reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of the Company's common stock.

The Company and its independent registered public accounting firm were not required to perform an evaluation of its internal control over financial reporting as of December 31, 2022 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, the Company cannot assure you that it has identified all material weaknesses or that there will not be additional material weaknesses in the future.

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

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

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

The Company 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 President and Chief Executive Officer, John Alam, M.D. Although the Company 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 the Company's headquarters is located. The Company also faces competition for the hiring of scientific and clinical personnel from universities and research institutions, many of which are near the Company's headquarters. The loss of the services of any member of the Company'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 the Company's business, operating results and financial condition.

The Company also relies on consultants and advisors to assist it in formulating and executing its business strategy. All of the Company'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, which may affect their ability to contribute to the Company.

As the Company continues to develop neflamapimod for the treatment of DLB, and also to expand into clinical trials for other CNS disorders, the Company 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 the Company's drug is approved. If the Company 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 the Company may develop or acquire, will be limited.

The Company 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, the Company may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of the Company'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 the Company's business plans or disrupt its operations.

Consumers may sue the Company 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 the Company 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 the Company 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. The Company has obtained limited product liability insurance coverage for its clinical trials, which the Company believes to be reasonable given its current operations. However, the Company's insurance coverage may not reimburse the Company or may not be sufficient to reimburse it for any expenses or losses it may suffer.

Although the Company 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 the Company'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 the Company's business and results of operations.

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

The Company 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, 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 the Company 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 the Company. If the Company 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 the Company's reputation. The Company 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 the Company 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 the Company, and the Company 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 the Company 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 the Company'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, the Company 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 the Company's drug candidates outside its control, require the Company to relinquish important rights, or may otherwise be on terms unfavorable to the Company. The Company may not be able to negotiate collaborations and alliances on acceptable terms, if at all. If the Company enters into a collaborative arrangement and it proves to be unsuccessful, the Company may have to delay, or limit the size or scope of, certain of its drug development activities.

Alternatively, if the Company 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 the Company on acceptable terms, if at all.

The Company'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 the Company'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 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. The Company is working to comply with the GDPR and other privacy and data protection laws and regulations that apply to it, and the Company 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 the Company's current policies and practices.

The Company'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 the Company 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 the Company's reputation, any of which could materially affect its business, financial condition, results of operations and growth prospects.

The Company'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.

The Company'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 the Company 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 the Company'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 the Company's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. If the Company 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, the Company'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 the Company's workforce began to work remotely, which has continued and is now considered its normal business. This could increase the Company's cyber security risk, create data accessibility concerns, and make the Company more susceptible to communication disruption.

To the extent that any disruption or security breach were to result in a loss of, or damage to, the Company's or its third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, the Company could incur liability including litigation exposure, penalties and fines, the Company 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 the Company's business, financial condition, results of operations or prospects. While the Company 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 the Company's business, financial condition or results of operations.

The Company'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, more recently, the COVID-19 pandemic 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 the Company'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 the Company's suppliers, possibly resulting in supply disruption. Any of the foregoing could harm the Company'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 the Company'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 the 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. For example, on March 27, 2020, former President Trump signed into law the 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, the TCJA was signed into law, which significantly reformed the Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in the Company'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, the Company 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 the Company's business, cash flow, financial condition or results of operations. The Company urges investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in the Company's Common Stock.

The Company 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 the Company's business, financial condition and results of its operations.

Risks Related to the Company's Product Development and Regulatory Approval

The Company 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, the Company's business will be materially harmed.

The Company has invested almost all of its efforts and financial resources to date in the development of neflamapimod for the treatment of DLB. To date, the Company 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. The Company'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.

The Company 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, the Company 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. The Company cannot be certain that it will be able to successfully complete any or all of these activities.

The Company 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 the Company may pursue. If the Company is unable to obtain the necessary regulatory approvals for neflamapimod, it will not be able to commercialize its drug. This would materially adversely affect the Company's financial position, and the Company 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 the Company's planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that the Company may pursue, will be successful. If the Company 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 the Company 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. The Company may experience difficulties in initiating and completing the clinical trials that it intends to conduct, and the Company 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, the Company 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 the Company's clinical studies to date, the Company 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, the Company initiated a confirmatory, hypothesis-testing Phase 2b randomized double-blind placebo-controlled clinical study of neflamapimod in subjects with DLB in the second quarter of 2023. The Company's Phase 2b trial may not be successful or the FDA may disagree with the Company's interpretation of the clinical trial data or how those data inform the design of a potentially pivotal Phase 3 clinical trial for the Company's lead indication.

Even if the Company's initial clinical trials results are confirmed in this Phase 2b clinical POC trial, the Company 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 the Company's clinical trials are deemed sufficient to support the submission of an NDA. The Company 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 the Company's failure to obtain regulatory approval to market neflamapimod for any of its planned indications, which would significantly harm the Company'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, the Company 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 the Company 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.

The Company 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.

The Company's approach to the treatment of DLB focuses in large part on neflamapimod's ability to inhibit the intra-cellular enzyme p38α. The expression of p38α is considered to be a critical contributor in the toxicity of inflammation, alpha-synuclein, amyloid-beta and tau to neurons and synapses, which the Company 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 p38α. In targeting synaptic dysfunction in this manner, the Company 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 the Company'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, the Company 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.

The Company has no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability.

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

As the Company continues to build its business, the Company 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 the Company's future operating performance.

Safety issues with neflamapimod or with any other product candidate the Company may develop or acquire in the future, or with product candidates or approved products of third parties that are similar to the Company'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 the Company 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 the Company 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 the Company'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 were 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 are 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 the recently initiated 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 the Company acquired an exclusive license from Vertex to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders, the Company submitted an IND application, to the DNP in February 2015. The DNP cleared the Company'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. the Company'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. the Company's recently initiated 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 the Company does 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 the Company continues the development and clinical trials of neflamapimod, treatment-related 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 the Company's clinical trials for neflamapimod in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of the Company'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 the Company 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 the Company to conduct additional clinical trials, or to implement a 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 the Company can promote the drug. Following a potential future drug product approval, regulatory authorities might also withdraw such approval and require the Company 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 the Company may develop or acquire, receives marketing approval and the Company 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;
- the Company 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;

- the Company may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable foreign regulatory authority may require the Company to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- the Company may decide to recall such product candidates from the marketplace after they are approved;
- the Company could be sued and held liable for injury caused to individuals exposed to or taking its product candidates; and
- the Company's reputation may suffer.

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

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. The Company 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 the Company 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, the Company 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.

The Company 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 the Company 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 the Company 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 the Company's CROs and other third parties, or the cost of clinical trials being greater than the Company anticipated;

- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of neflamapimod or the Company'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 the Company's product candidates may produce negative or inconclusive results, and the Company 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 the Company's product candidates may be larger than the Company 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;

- the Company's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to the Company in a timely manner, or at all;

- regulators, the IRB or a Data Safety Monitoring Board if one is used for the Company's clinical trials, may require that the Company 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 the Company's product candidates or other materials necessary to conduct clinical trials of the Company'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 the Company's CMOs or the Company to make any necessary changes to such manufacturing process;

- the FDA or comparable foreign regulatory authorities may require the Company 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 the Company's clinical trial design and the Company'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 the Company's clinical trials.

If the Company is required to conduct additional clinical trials or other nonclinical studies of neflamapimod in various disease conditions beyond those that the Company currently contemplates, if it is unable to successfully complete clinical trials of the Company'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, the Company 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 the Company'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.

The Company 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 the Company's control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on the Company's ability to enroll a sufficient number of research participants who remain in the study until its conclusion. The Company 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 the Company 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;
- the Company'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 the Company 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, including in our ongoing Phase 2b trial, may result in increased costs or program delays, which could have a harmful effect on the Company's ability to develop a product candidate or could render further development impossible.

If the Company 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. the Company's inability to fully take advantage of these incentive programs may require the Company 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 the Company's clinical trials that the Company 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 the Company's clinical trials for neflamapimod are completed as planned, including a future Phase 3 trial, the Company cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

In addition, from time-to-time the Company 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. the Company 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 the Company 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 the Company's business prospects. Accordingly, the results from the completed preclinical studies and clinical trials for the Company's product candidates may not be predictive of the results the Company may obtain in later stage trials. Its clinical trials may produce negative or inconclusive results, and the Company 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 the Company'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 the Company in general.

In addition, the information the Company 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 the Company determines is the material or otherwise appropriate information to include in its disclosure, and any information the Company 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 the Company reports differ from later, final or actual results, or if others, including the FDA and comparable foreign regulatory authorities, disagree with the conclusions reached, the Company'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.

The Company 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, the Company's business will be harmed.

Although the Company 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. The Company 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. The Company's reliance on CROs for clinical development activities limits its control over these activities, but it remains responsible for ensuring that each of the Company's trials is conducted in accordance with the applicable protocol, legal and regulatory and scientific standards. The Company does not control these third parties, and they may not devote sufficient time and resources to the Company'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 the Company 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 the Company's requisite quality standards, including due to geopolitical events, natural disasters, public health emergencies or pandemics, or poor workforce relations or human capital management.

The Company 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 the Company 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 the Company 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 the Company'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 the Company's business, financial condition, results of operations and prospects.

If the Company'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 the Company's clinical protocols or regulatory requirements or for any other reason, the Company'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, the Company'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.

The Company has employed several different contract research organizations for clinical trial services. Although the Company believes there are numerous alternatives to provide these services, in the event that it seeks a new CRO, the Company 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 the Company intends to carefully manage its relationships with its CROs, there can be no assurance that the Company 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.

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

The Company has no manufacturing facilities and does not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. The Company 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 the Company 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.

The Company further intends to rely on third-party 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 the Company's neflamapimod program, or any other product candidate that the Company may develop or acquire in the future, in conformity to its specifications and the applicable regulatory requirements, the Company 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 the Company 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 the Company'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 the Company's product candidates into the market. In the event of such failure, the Company 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, the Company 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 the Company'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, the Company could be materially adversely affected and any of its clinical trials could be materially delayed. Such an extended shut down may force the Company to procure a new research and development facility or another manufacturer or supplier, which could be time-consuming. During this period, the Company may be unable to receive investigational neflamapimod supplies or any other product candidates it may develop or acquire.

The recently initiated Phase 2b clinical trial is being conducted with a drug substance (the API) already manufactured in 2019 at a third-party CMO. In addition, the Company has 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. The Company anticipates utilizing the company for clinical trials beyond the Phase 3 clinical trial in DLB, as well potentially for commercial use. However, supplies of the neflamapimod drug substance could be interrupted from time to time, and the Company 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 the Company's product candidates, if approved, or result in a shortage in supply, which would impair its ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair the Company's ability to cost effectively manufacture its product candidates.

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

While the Company believes that there are multiple alternative sources available for manufacturing of both drug substance and drug product in its neflamapimod program, the Company 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 the Company's development and commercialization efforts.

Although the Company 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 the Company'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 the Company, 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 the Company's suppliers, manufacturers, distributors or regulatory service providers experience could delay or interrupt supply of materials necessary to produce the Company's product candidates. Failure to obtain the needed quantities of the Company's product candidates could have a material and adverse effect on its business, financial condition, results of operations and prospects.

If the Company 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 the Company'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 the Company 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, the Company 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 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 the Company's development plans and, thereby, delay the Company'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, the Company 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 the Company 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 the Company 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 the Company'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 the Company 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 not-compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or the Company. If the Company or its third-party providers, including the Company's CMOs, fail to comply fully with applicable regulations, then the Company may be required to initiate a recall or withdrawal of its products.

The Company 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, the Company 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 the Company 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 the Company receives marketing approval for neflamapimod, the Company 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 the Company 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 the Company'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 the Company's product candidates. If the Company 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 the Company's business, prospects and ability to achieve or sustain profitability.

If the Company 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.

The Company 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, the Company 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 the Company's own sales, marketing and distribution functions, including the Company'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 the Company 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 the Company is unable to establish adequate sales, marketing and distribution capabilities, either on its own or in collaboration with others, the Company will not be successful in commercializing neflamapimod, if it is ultimately approved, and it may never become profitable. The Company 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, the Company may be unable to compete successfully against these more established companies.

Risks Related to the Company's Commercialization Plans

The Company's business operations are subject to applicable healthcare laws and regulations. If neflamapimod is approved, the Company 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 the Company fails to comply with applicable regulations.

Although the Company 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 the Company 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 the Company obtains marketing approval. The Company's future arrangements with such third parties may expose the Company 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 the Company 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 Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;

- 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, which 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 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 the Company'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 the Company for violation of these laws, even if the Company successfully defends against it, could cause the Company 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 the Company's product candidates, the Company 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 the Company'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 the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to the Company, 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 the Company's operations. If any of the physicians or other healthcare providers or entities with whom the Company 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 the Company develops receives marketing approval, it may fail to achieve the level of acceptance necessary for commercial success.

If neflamapimod, or any other product candidate the Company 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 the Company's drug does not achieve an adequate level of acceptance, the Company 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;
- the Company'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 the Company's sales, marketing and distribution capabilities, either internally or in collaboration with others;
- any restrictions on the use of the Company's product together with other medications; and
- any restrictions on the distribution of the Company's product such as those imposed under a mandatory REMS program.

If neflamapimod or any other product candidate that the Company 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 the Company will not generate sufficient revenues to achieve profitability. Because the Company expects sales of its product candidates, if approved, to generate substantially all of its revenues for the foreseeable future, the failure of the Company's product candidates to find market acceptance would materially harm its business.

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

The Company 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 the Company'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 the Company's product candidates would be limited to the therapeutic indications examined in the Company's clinical trials and as determined by the FDA, which would not permit the Company 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 the Company's product candidates may not ultimately be amenable to treatment with the Company's product candidates. Even if the Company receives regulatory approval for any of its product candidates, such approval could be conditioned upon label restrictions that materially limit the addressable patient population. The Company's market opportunity may also be limited by future competitor treatments that enter the market. If any of the Company's estimates prove to be inaccurate, the market opportunity for any product candidate that the Company or its strategic partners develop could be significantly diminished and have an adverse material impact on its business.

The Company 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 the Company 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, the Company anticipates that more companies will enter the DLB market in the future. The Company'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 the Company may obtain approval for neflamapimod, which could result in their establishing or strengthening a commercial position before the Company 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 The Company's ability to advance neflamapimod commercially. If the Company 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 the Company 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 the Company'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. The Company'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 the Company's ability to successfully commercialize neflamapimod and any other potential future product candidates. Assuming the Company 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. the Company 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, the Company 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, the Company may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of the Company's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the Company's business could be harmed, possibly materially. As a result, the Company 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 the Company is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder the Company's ability to recoup its investment in its product candidates, even after obtaining regulatory approval.

The market for any products for which the Company 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 the Company 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 the Company shows improved efficacy or improved convenience of administration compared to existing treatments for its target indications, pricing of existing drugs may limit the amount the Company will be able to charge for neflamapimod.

If the Company 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 the Company'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 the Company to obtain marketing approval of and commercialize its product candidates, if approved, and also affect the prices it may set.

There have been, and the Company 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 the Company'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 the Company may develop or acquire. The Company 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 the Company 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, the Company 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 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.

The Company'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 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 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 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 the Company.

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.

The Company 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 the Company from being able to generate revenue, attain profitability or commercialize its product candidates. Further, if the Company 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 the Company 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 the Company's business may rely, which could negatively impact the Company'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, the NIA and other government agencies on which the Company'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 the Company'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 NIA to disburse funds for our clinical trial and for the FDA to timely review and process the Company's regulatory submissions, which could have a material adverse effect on the Company's business. Further, in the Company'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.

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

The Company has in the past and 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 U.S. or that any comparable non-U.S. regulatory authority will accept data form 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 standard-of-care; cultural differences in medical practice and clinical research; diminished protection of intellectual property rights; and compliance with general local legal requirements.

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

The Company'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 the Company 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. The Company'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, the Company's dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the 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 the Company's employees, agents, contractors, or collaborators, or those of the Company'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 the Company, its officers, or its employees, the closing down of the Company'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 the Company's ability to offer its products in one or more countries and could materially damage the Company'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 the Company's Intellectual Property

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

The Company relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to its neflamapimod drug development program. The Company'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. The Company 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.

The Company 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. The Company 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, the Company 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.

The Company's issued patents and patent applications remain subject to uncertainty and continued monitoring. The Company'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 the Company may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The Company 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 the Company'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 the Company 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 the Company could deprive it of rights necessary for the successful commercialization of neflamapimod, or any other product candidates it may develop. Further, if the Company 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, the Company 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 the Company'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 the Company's ability to prevent others from using or commercializing similar or identical technology and products.

The Company 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 the Company's product candidates, if approved, could affect the Company'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 the Company'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 the Company's products.

There is no composition matter patent protection that covers neflamapimod. Rather, the Company'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. The Company 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 the Company's current or future product candidates, these candidates may be open to competition from other products. As a result, the Company's patent portfolio may not provide the Company with sufficient rights to exclude others from commercializing products similar or identical to the Company's.

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

The Company is party to an Option and License Agreement with Vertex, pursuant to which the Company 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 License Agreement, the Company 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 License 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 License 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 License Agreement also provides that in the event the Company 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, the Company must be diligent in meeting its obligations under the License Agreement. Any uncured, material breach under the License Agreement could result in the loss of certain of its rights to neflamapimod and could compromise the Company's development and commercialization efforts. This in turn would have an adverse effect on the Company's business, which could be material.

The Company may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or the Company 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

The Company's commercial success depends, in part, upon the Company'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 the Company is not currently subject to any pending intellectual property litigation, and is not aware of any such threatened litigation, the Company 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 the Company 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 the Company. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that the Company's product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

The Company may be subject to third-party claims including infringement, interference or derivation proceedings, reexamination proceedings, post-grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if the Company 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 the Company's ability to commercialize the applicable product candidate unless the Company 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 the Company'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 the Company.

As a result of patent infringement claims, or in order to avoid potential infringement claims, the Company 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 the Company's competitors access to the same intellectual property rights. If the Company 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 the Company's business operations, which could harm the Company's business significantly. In addition, if the breadth or strength of protection provided by the Company's patents and patent applications is threatened, it could dissuade companies from collaborating with the Company to license, develop or commercialize current or future product candidates.

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

Finally, even if resolved in the Company's favor, litigation or other legal proceedings relating to intellectual property claims may cause the Company 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 the Company's reputation, harm its business, and the price of its common stock could be adversely affected.

The Company 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 the Company's ability to develop, manufacture and market its product candidates.

From time to time, the Company may identify patents or applications in the same general area as its products and product candidates. The Company 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 the Company, however, a court may disagree with the Company's determinations. Further, while the Company 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, the Company's determination may be incorrect, and the issuing patent may be asserted against the Company. The Company cannot guarantee that it will be able to successfully settle or otherwise resolve such infringement claims. If the Company 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. The Company 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 the Company 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 the Company's ability to protect its product candidates.

The Company'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 the Company's patents or narrow the scope of its patent protection.

As an example, the AIA, which was passed in September 2011, resulted in significant changes to the U.S. patent system. Pursuant to the MA, 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 the Company could therefore be awarded a patent covering an invention of the Company's even if the Company made the invention before it was made by the third party. This requires the Company 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 the Company's patent applications and the enforcement or defense of its issued patents.

In addition, the laws of foreign countries may not protect the Company'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 the Company's ability to obtain new patents in the future that may be important for its business.

The Company 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 the Company's product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use the Company'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 the Company has patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with the Company's product candidates, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Although the Company intends to protect its intellectual property rights in its expected significant markets, the Company cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which the Company may wish to market its product candidates. The Company 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 the Company to stop the infringement of its patents or marketing of competing products in violation of the Company'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 the Company's business, could put the Company'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 the Company. The Company 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 the Company is forced to grant a license to any third parties with respect to any patents relevant to the Company's business, its competitive position may be impaired.

The Company's reliance on third parties requires the Company 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.

The Company may rely on trade secrets or confidential know-how to protect various aspects of its business, especially where patent protection is believed by the Company to be of limited value. Because it relies on third parties to manufacture neflamapimod and any future product candidates, and the Company may also collaborate with third parties on the development of neflamapimod and any future product candidates, the Company must, at times, share trade secrets with such parties. The Company may also conduct joint research and development programs that require it to share trade secrets under the terms of the Company'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, the Company'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 the Company prior to beginning research or disclosing proprietary information. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose the Company'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 the Company's efforts to protect its trade secrets, the Company's competitors may discover the Company's trade secrets, either through breach of the Company's agreements with third parties, independent development or publication of information by any of its third-party collaborators. A competitor's discovery of the Company'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 the Company's exclusive rights and limit its ability to contract with non-U.S. manufacturers.

The Company received a grant from the NIA to support its recently initiated Phase 2b clinical trial for treatment in patients with DLB. Pursuant to the 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 the Company 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 the Company 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 the Company's intellectual property rights that are generated through the use of U.S. government funding or grants, the Company could be required to license or sublicense intellectual property discovered or developed by it or that it licenses on terms unfavorable to the Company, and there can be no assurance that the Company 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 the Company to expend substantial resources. Should any of these events occur, it could significantly harm the Company'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 the Company's ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

General Risk Factors

The Company's stock price may be volatile, there may be limited liquidity in the trading market for the Company's common stock, and the market price of its common stock may drop for a period of time following the Merger.

The market price of the Company's common stock may be subject to significant fluctuations. 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 Company's common stock to fluctuate include among others:

- the ability of the 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 Company or its partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- failure of any of the Company's product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure by the Company to maintain its existing third-party license, manufacturing and supply agreements;
- failure by the Company or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to the 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 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 Company or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the 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 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 Company or its stockholders in the future;
- trading volume of the Company's common stock;
- adverse publicity relating to the 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 Company's financial results.

After completion of the Merger, the market price of Company's common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors. First, the Company has relatively few shares of common stock outstanding in the "public float" since most of the shares are 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. An active trading market for the 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.

Second, the Company may 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 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.

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

The trading market for the 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 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 Company will not have any control over the analysts, or the content and opinions included in their reports. The price of the 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 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 Company's stock price to decline.

If existing stockholders of the Company sell, or indicate an intention to sell, substantial amounts of the Company's common stock in the public market after certain legal and contractual restrictions on resale lapse, the trading price of the common stock of the Company could decline. Based on shares outstanding immediately after the closing of the Merger, the Company had a total of approximately 5.7 million shares of common stock outstanding. Approximately 2.9 million of such shares of outstanding common stock are freely tradable, without restriction, in the public market. Approximately 1.1 million of such shares of outstanding common stock are held by directors, executive officers of the Company and other affiliates and are subject to volume limitations under Rule 144 promulgated under the Securities Act and various vesting agreements.

The Company may choose to waive certain of its rights under the lock-up agreements signed by certain equityholders.

In connection wither Merger, certain directors, executive officers and principal stockholders of the Company and EIP 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 Company's common stock for up to 180 days following the closing of the Merger. However, in certain circumstances, the Company may choose to waive its rights under any or all of such lock-up agreements, either in whole or in part. In such an event, the holders of those shares may be permitted to sell or transfer the shares of common stock received in the Merger sooner than they otherwise would, which could result in a decrease to the Company's stock price. For example, in July 2023, the Company waived certain obligations under the lock-up agreement of AI EIPP Holdings LLC and its affiliates.

After completion of the Merger, the ownership of the Company common stock is 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 Company stock price to decline.

Executive officers and directors of the Company and their affiliates own or control approximately 32.6% of the outstanding shares of the Company common stock immediately following the closing of the Merger. Certain other former stockholders of EIP own or control approximately 64.2% of the outstanding shares of the Company common stock immediately following the closing of the Merger. Additionally, Dr. Alam and Dr. Sylvie Grégoire, our Chair, who are married, hold a significant interest in the Company's common stock on a fully diluted basis. For as long as Dr. Alam and Dr. Grégoire maintain a significant interest in the Company, they may be in a position to affect the Company's governance and operations. Accordingly, these stockholders, in the aggregate, may 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 Company assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the Company, even if such a change of control would benefit the other stockholders of the Company. The significant concentration of stock ownership may adversely affect the trading price of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

The Company does not anticipate that it will pay any cash dividends in the foreseeable future.

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

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by Internal Revenue Service, the U.S. Treasury Department, and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect the 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 Company's business, cash flow, financial condition, or results of operations.

The Merger may have adverse tax consequences for former holders of EIP securities.

Subject to certain limitations and qualifications described in the section titled "*The Merger — Material U.S. Federal Income Tax Consequences of the Merger*" beginning on page 140 of our proxy statement/prospectus/information statement, dated July 13, 2023 and previously filed with the SEC, the Merger is believed to qualify as a reorganization within the meaning of Section 368(a) of the Code. This opinion is based on certain facts and representations on customary factual assumptions. If the Merger were to fail to so qualify, then each pre-Merger U.S. 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 the Company's 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, if any, and (2) its adjusted tax basis in the shares of EIP common stock surrendered in exchange therefor.

Due to the Merger potentially resulting in an ownership change under Section 382 of the Code, the pre-merger NOL carryforwards and certain other tax attributes of both EIP and Diffusion may be subject to limitation.

As of December 31, 2022, Diffusion and EIP had U.S. federal NOL carryforwards of approximately $34.2 million and $38.2 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), 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 may have resulted in such an ownership change and, accordingly, the Company's NOL carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use after the Merger. The Company's NOL carryforwards may also be subject to limitation as a result of prior or future shifts in equity ownership, as well. Consequently, even if the Company achieves profitability, it may not be able to utilize a material portion of its 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 Company's existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Now that 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 the Company, EIP and Merger Sub contained in the Merger Agreement or any certificate or instrument delivered pursuant to the Merger Agreement terminated at the effective time of the Merger. To the extent that any such party's breach of any representations and warranties is discovered or occurs following the closing of the Merger, there is no mechanism pursuant to which the other parties can pursue recourse or remedy.

The Company's business may be affected from time-to-time by government investigations and litigation with third parties, including our ongoing matter with Paul Feller.

The Company may from time to time receive inquiries and subpoenas and other types of information requests from government authorities and other third parties and may become subject to claims and other actions related to its business activities. While the ultimate outcome of investigations, inquiries, information requests and legal proceedings is difficult to predict, defense of litigation claims (even if ultimately successful) can be expensive, time-consuming and distracting, and adverse resolutions or settlements of those matters may result in, among other things, modifications to business practices, costs and significant payments, any of which could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

For example, in August 2014, Paul Feller, the former Chief Executive Officer of the Company's legal predecessor, filed a complaint asserting various causes of action related to his past affiliations with the Company's legal predecessor. While the Company believes the claims in this matter are without merit and is defending itself vigorously, 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.

In addition, the Company's stockholders may serve demands and/or file lawsuits challenging the Merger, which may name the Company, EIP, members of the Company's former or current board of directors, members of the EIP board of directors and/or others as defendants. No assurance can be made as to the outcome of such demand or lawsuits, including the amount of costs associated with defending, settling, or any other liabilities that may be incurred in connection with the litigation or settlement of such claims, if any.

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

The 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 Company maintain effective disclosure controls and procedures and internal control over financial reporting. The 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. This will require that the Company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. The Company may experience difficulty in meeting these reporting requirements in a timely manner.

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

Provisions in the 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 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 Company's common stock, thereby depressing the market price of its common stock. In addition, because the 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 Company's stockholders to replace or remove its current management by making it more difficult for stockholders to replace members of the Company's board of directors. Among other things, these provisions:

- allow the authorized number of the 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 Company's board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to the Company's board of directors;
- limit who may call stockholder meetings and the Company stockholders' ability to act by written consent;
- authorize the 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 Company's board of directors; and
- require the approval of the holders of at least 2/3 of the votes that all the Company's stockholders would be entitled to cast to amend or repeal specified provisions of the Company's certificate of incorporation, as amended, or for stockholders to amend or repeal the Company's amended and restated bylaws.

Moreover, because the Company 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.

The 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 Company's certificate of incorporation provides that, unless the 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 Company's behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of the 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 Company's 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 Company's stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with the Company or its directors, officers or employees, which may discourage such lawsuits against the Company and its directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in the Company's certificate of incorporation to be inapplicable or unenforceable in an action, the 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.

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

One or more of the Company's stockholders may from time to time seek to acquire a significant or controlling stake in the Company, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes to the Company'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 the Company's operations and divert the attention of the Company board of directors and senior management, and could adversely affect the Company's operations, financial condition, and the value of the Company Common Stock. For example, in November 2022, LifeSci Special Opportunities Master Fund Ltd., a the Company stockholder, informed the Company of its intent to nominate an alternative slate of directors for election at the Company's 2022 annual meeting of stockholders, which was subsequently withdrawn following the parties entering into a settlement agreement on December 11, 2022.

The Company 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.

The Company holds its cash and cash equivalents that we use to meet our working capital needs in deposit accounts at multiple financial institutions. The balance held in these accounts may exceed the FDIC, standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which the Company holds such funds fails or is subject to significant adverse conditions in the financial or credit markets, the Company 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 the Company's short-term liquidity and ability to meet its obligations.

For example, on March 10, 2023, Silicon Valley Bank, 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 Silicon Valley Bank 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. While the Company did not hold any of its funds in accounts with either of these institutions, if financial institutions in which the Company holds funds for working capital were to fail, the Company cannot provide any assurances that such governmental agencies would take action to protect its uninsured deposits in a similar manner.

The Company also maintains investment accounts with other financial institutions in which it holds its investments and, if access to the funds the Company uses for working capital is impaired, the Company 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.

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

The Company's common stock is currently listed on the Nasdaq Capital Market. To maintain this listing, the Company is required to meet certain listing requirements related to, among other things, the trading price of the Company's common stock, the Company's market capitalization and certain corporate governance-related requirements. In the event that the Company's common stock is delisted from Nasdaq for a failure to meet such requirements and is not eligible for quotation or listing on another market or exchange, trading of the Company's 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 the Company's stockholders to dispose of, or obtain accurate price quotations for, the Company's common stock. There would likely also be a reduction in the Company's coverage by securities analysts and the news media, which could cause the price of the Company's common stock to decline further.

The Company may not be able to enter into a transaction with a suitable acquiror or licensee for its product candidate TSC or any transaction entered into may not be on terms that are favorable to the Company.

As previously announced, in connection with Diffusion's strategic review process during 2022-23, Diffusion made the strategic decision to voluntarily pause significant portions of the development program for TSC, Diffusion's lead drug candidate prior to the Merger. Currently, the Company 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 the Company's management has contacted numerous parties to assess their potential interest in such a transaction, to date, the Company has been unable to identify an interested counterparty. Furthermore, even if the Company 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 the Company will enter into any transaction as a result of these effort or that any transaction involving the Company's TSC-related assets will be entered into or, if entered into, will be on terms that are favorable to the Company. Furthermore, the Company 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES.

On July 10, 2023, prior to completion of the Merger, EIP issued and sold 63,422 shares of common stock at $12.78 per share (in each case, as adjusted for the Exchange Ratio) for gross proceeds of approximately $0.8 million. Upon consummation of the Merger, all such shares converted into shares of the Company's common stock on the same terms as all other EIP Common Stock.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None noted.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6: EXHIBITS

Exhibit No.	Description
3.1	Certificate of Merger, dated August 16, 2023 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
3.2	Certificate of Amendment, dated August 16, 2023 to the Certificate of Incorporation, as amended, of Diffusion Pharmaceuticals Inc. to implement the Reverse Stock Split (incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
3.3	Certificate of Amendment, dated August 16, 2023 to the Certificate of Incorporation, as amended, of Diffusion Pharmaceuticals Inc. to implement the name change (incorporated by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
3.4	Bylaws, as amended, of CervoMed Inc. (incorporated by reference to Exhibit 3.5 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
4.2	Form of AI EIPP Holdings LLC Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
10.1	Subscription Agreement, dated July 10, 2023
10.2	Form of Indemnification Agreement between the Company and each of its directors and officers (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed with the SEC on August 17, 2023)
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).
32.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).
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 and contained in Exhibits 101).

* XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

** Furnished, not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CERVOMED INC.

Date: November 13, 2023

By: */s/ John Alam*
John Alam
President and Chief Executive Officer
(Principal Executive Officer)

By: */s/ William Tanner*
William Tanner
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

FORM OF SUBSCRIPTION AGREEMENT

EIP PHARMA, INC.

To: EIP Pharma, Inc.
20 Park Plaza, Suite 424
Boston, Massachusetts 02116

This Subscription Agreement (the "Agreement"), dated July [__], 2023, is made between EIP Pharma, Inc., a Delaware corporation ("we" or the "Company"), and the undersigned prospective purchaser ("you" or the "Undersigned") who is subscribing for that number of shares of Common Stock, $0.001 par value per share, of the Company (the "Shares") set forth on the execution page hereto. The purchase price will be U.S. $1.47 per Share (the "Purchase Price"). The Company intends to raise an aggregate amount of up to $810,000, but the Company may increase the aggregate amount raised in its sole discretion. This subscription is submitted to you, in accordance with, and subject to, the terms and conditions described in this Agreement.

The Undersigned and the Company agree and represent as follows:

A. **Terms of Subscription**.

1. The Undersigned hereby irrevocably subscribes for and agrees to purchase the Shares at a purchase price of U.S. $1.47 per Share (the "Subscription") for the total purchase price of set forth on the execution page hereto. Payment for the Shares shall be received by the Company from the Undersigned by wire transfer of immediately available funds or other means approved by the Company at or prior to the Closing, in the amount as set forth on the execution page hereto (the "Payment"). The Undersigned may send payment prior to the Closing to be held by the Company in escrow pending acceptance of the subscription. If the subscription is not accepted, the Company will return the payment to the Undersigned without any interest thereon. The Company's wiring instructions are as follows:

ABA: [_____]
Bank Name: [_____]
Bank Address: [_____]
Beneficiary: [_____]
Beneficiary's Address: [_____]
Account to Credit: [_____]

The initial closing of the purchase of the Shares is anticipated by July [__], 2023 (the "Closing"), but may be extended in the Company's sole discretion.

2. Upon the Closing, the Undersigned (a "Purchaser") will be issued a stock certificate for the number of Shares purchased in its name, and the name of such Purchaser will be entered on the stock transfer books of the Company as the record owner of such Shares.

B. **Contractual Restrictions Applicable to the Shares; Confidentiality**.

The Undersigned agrees that as a condition to the purchase and sale of the Shares to become a party to (i) the Investors' Rights Agreement by and among the Company and the Investors listed therein (as such term is defined therein) (the "IRA") and (ii) the Voting Agreement by and among the Company and the Stockholders listed therein (as such term is defined therein) (the "Voting Agreement," together with the IRA, the "Investor Documents"), each dated as of April 2, 2018, by execution of the counterpart signature page enclosed herewith. The Undersigned acknowledges that he, she or it has read and understands the Investor Documents, which set forth certain rights, preferences, restrictions and limitations on the Shares, including the ability to transfer or sell them in the future. If the Undersigned is already a party to the Investor Documents, the Undersigned acknowledges and agrees that the Shares purchased hereunder are also subject to the terms and conditions of the Investor Documents.

The Undersigned hereby agrees to protect and safeguard the Company's confidential information and agrees not to disclose or use the Company's confidential information, or permit any third party to access or use such confidential information.

C. **Qualification to Purchase**.

The offering of the Shares is being conducted pursuant to an exemption from the securities registration requirements provided by one or more rules promulgated under section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The Company is requiring that all purchasers in the private placement qualify as, an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act. "*Accredited Investor*" shall mean any person who comes within any of the following categories, or who the issuer reasonably believes comes within any of the following categories, at the time of the sale of the Shares to that person. The Undersigned represents that he, she or it is an "accredited investor" for the following reason(s):

(Please certify with your initials that one or more of (i) through (v) below apply to you).

_____ (i) Any organization described in Section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000;

_____ (ii) Any natural person whose individual net worth, or joint net worth with that person's spouse, at the time of his purchase exceeds $1,000,000;

_____ (iii) Any natural person who had an individual income in excess of $200,000 in each of the two most recent years or joint income with that person's spouse in excess of $300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year;

_____ (iv) Any trust with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person who has such knowledge and experience in financial and business matters so that the person is capable of evaluating the merits and risks of the prospective investment; or

_____ (v) Any entity in which all of the equity owners are accredited investors.

D. **Experience and Suitability; Investment Purpose**.

The Undersigned has such knowledge and experience in financial and business matters to evaluate the merits and risks of an investment in the Shares and to make an informed decision relating thereto. The Undersigned has the financial capability for making the investment and can afford a complete loss of the investment. The investment is a suitable one for the Undersigned.

The Undersigned acknowledges that he, she or it is not purchasing the Shares as a result of any General Solicitation or General Advertising (as such terms are used and defined in Rule 502(c) of Regulation D under the Securities Act) and the Undersigned is acquiring the Shares for the Undersigned's own account for the purpose of investment and not with a view to, or for resale in connection with, the distribution thereof, nor with any present intention of distributing or selling the Shares. The Undersigned confirms that he, she or it is not relying on any communication (written or oral) of the Company or any of its affiliates, as investment advice or as recommendation to purchase the Shares. The Undersigned understands that the Shares have not been registered under the Securities Act or the securities laws of any state and may never be so registered. The Undersigned hereby agrees not to make any sale, transfer or other disposition of any such Shares unless either (i) the Shares first shall have been registered under the Securities Act and all applicable state securities laws, or (ii) an exemption from such registration is available, and the Company has received such documents and agreements from the Undersigned and the transferee as the Company reasonably requests at such time.

The Undersigned represents and warrants that if required by applicable securities legislation, regulatory policy or order by any securities commission, stock exchange or other regulatory authority, he, she or it will execute, deliver, file and otherwise assist the Company in filing reports, questionnaires, undertakings, and other documents with respect to the issuance of the Shares. The Undersigned represents and warrants that he, she or it is entitled to subscribe for the Shares under the laws of all relevant jurisdictions which apply to it, and that he, she or it has not taken any action or omitted to take any action which will or may result in the Company or any of its respective directors, officers, agents, employees or advisers acting in breach of the legal and regulatory requirements of any jurisdiction in connection with the placement of the Shares or the Company's acceptance of the Purchase Price.

The Undersigned represents and warrants that he, she or it is resident in the state set forth below and is receiving the Shares in such state, as applicable.

The Undersigned hereby acknowledges that the representations and warranties contained in this Agreement are made by the Undersigned with the intent that the representations and warranties may be relied upon by the Company and its agents in determining the Undersigned's eligibility to purchase the Shares. The Undersigned represents and warrants that his, her or its representations and warranties are true at the time of Closing with the same force and effect as if they had been made by he, she or it at the Closing time and that they shall survive the purchase by he, she or it of the Shares and shall continue in full force and effect notwithstanding any subsequent disposition by he, she or it of the Shares.

E. **No Need for Liquidity**.

The Undersigned is aware that this investment may not be readily liquidated in case of an emergency and that the Shares being purchased may have to be held for an indefinite period of time. The Undersigned's overall commitment to investments which are not readily marketable is not excessive in view of its net worth and financial circumstances and the purchase of the Shares will not cause such commitment to become excessive. In view of such facts, the Undersigned has adequate means of providing for any current needs, anticipated future needs and possible contingencies and emergencies and has no need for liquidity in the investment in the Shares. The Undersigned is able to bear the economic risk of this investment, including a complete loss of its investment or the possibility that there may never be any liquidity in this investment.

F. **Opportunity to Investigate**.

Prior to the execution of this Agreement, the Undersigned and/or the Undersigned's advisors have reviewed the information about the Company in this Agreement, have reviewed the Investor Documents, have received and carefully considered the financial and business information about the Company that they have requested and have had the opportunity to ask questions of, and receive answers from, representatives of the Company concerning the terms and conditions of this transaction, and the finances, operations, business and prospects of the Company. The Undersigned and/or the Undersigned's advisors have also had the opportunity to obtain whatever additional information the Undersigned or its advisors have deemed necessary to verify the accuracy of information furnished about the Company. Accordingly, the Undersigned has independently evaluated the risks of purchasing the Shares, has consulted with the Undersigned's own advisors, and the Undersigned has received information with respect to all matters which the Undersigned considers material to the Undersigned's decision to make this investment and as a result of which has been satisfied regarding information about the Company.

G. **Representations and Warranties of the Company**.

The Company hereby represents and warrants to the Undersigned that the following representations are true and complete as of the date hereof and as of the Closing, unless otherwise indicated. The Undersigned acknowledges that except as explicitly set forth in this Agreement the Company makes no representation or warranty of any kind or nature.

(a) Organization, Good Standing, Corporate Power and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business as presently conducted and as proposed to be conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a material adverse effect.

(b) Corporate Action. The Company has all necessary corporate power and authority, and has taken all corporate action required, for the due authorization, execution, delivery and performance of this Agreement and any other agreements executed in connection herewith, and for the due authorization and issuance of the Shares. This Agreement, the Investor Documents, and any other agreements executed by the Company in connection herewith, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies, or (iii) to the extent the indemnification provisions contained in the Investor Documents may be limited by applicable federal or state securities laws.

(c) Governmental Consents and Filings. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required on the part of the Company in connection with the consummation of the transactions contemplated by this Agreement, except for filings pursuant to Regulation D of the Securities Act, and applicable state securities laws, which have been made or will be made in a timely manner.

(d) Valid Issuance of Securities. The Shares, when issued, sold and delivered in accordance with the terms hereof for the consideration expressed herein, will be duly and validly issued, fully paid and nonassessable and free of restrictions on transfer other than restrictions on transfer under this Agreement, the Investor Documents, applicable state and federal securities laws and liens or encumbrances created by or imposed by the Undersigned.

(e) Compliance with Other Instruments. The Company is not in violation or default (i) of any provisions of its Certificate of Incorporation or Bylaws, (ii) of any instrument, judgment, order, writ or decree, (iii) under any note, indenture or mortgage, or (iv) under any lease, agreement, contract or purchase order to which it is a party or by which it is bound, or (v) to its knowledge, of any provision of federal or state statute, rule or regulation applicable to the Company, the violation of which would have a material adverse effect. The execution, delivery and performance of this Agreement and the Investor Documents and the consummation of the transactions contemplated thereby will not result in any such violation or be in conflict with or constitute, with or without the passage of time and giving of notice, either (i) a default under any such provision, instrument, judgment, order, writ, decree, contract or agreement; or (ii) an event which results in the creation of any lien, charge or encumbrance upon any assets of the Company or the suspension, revocation, forfeiture, or nonrenewal of any material permit or license applicable to the Company.

(f) No Brokers or Finders. No person has or will have, as a result of the transactions contemplated by this Agreement based on actions taken by the Company or, to the Company's knowledge anyone acting on its behalf, any right, interest or valid claim against or upon the Undersigned or the Company for any commission, fee or other compensation as a finder or broker; and the Company agrees to indemnify and hold the Undersigned harmless against any such commissions, fees or other compensation.

(g) Capitalization; Status of Capital Stock. The authorized capital of the Company consists of:

(i) 36,000,000 shares of Common Stock, 4,501,652 shares of which are issued and outstanding immediately prior to the Closing. All of the outstanding shares of Common Stock have been duly authorized, are fully paid and nonassessable and were issued in compliance with all applicable federal and state securities laws.

(ii) 28,941,797 shares of Preferred Stock, of which (i) 17,033,883 shares have been designated Series A-1 Preferred Stock, all of which are issued and outstanding immediately prior to the Closing, (ii) 2,916,686 shares have been designated Series A-2 Preferred Stock, all of which are issued and outstanding immediately prior to the Closing, and (iii) 8,991,228 shares have been designated Series B Preferred Stock, all of which are issued and outstanding immediately prior to the Closing. The rights, privileges and preferences of the Preferred Stock are as stated in the Company's Certificate of Incorporation and as provided by the Delaware General Corporation Law.

(iii) The Company has reserved 1,435,000 shares of Common Stock for issuance to officers, directors, employees and consultants of the Company pursuant to the Company's 2018 Employee, Director and Consultant Equity Incentive Plan duly adopted by the Board of Directors of the Company and approved by the Company stockholders (the "Stock Plan"). Of such reserved shares of Common Stock, 995,000 are subject to outstanding awards under the Stock Plan and 440,000 remain available for issuance to officers, directors, employees and consultants pursuant to the Stock Plan.

(iv) Except for (A) the conversion privileges of the Company's Preferred Stock and warrants, (B) the rights provided in Section 4 of the IRA, and (C) the securities and rights, privileges and preferences of the Company's Preferred Stock as stated in the Company's Certificate of Incorporation and as provided by the Delaware General Corporation Law, there are no outstanding options, warrants, rights (including conversion or preemptive rights and rights of first refusal or similar rights) or agreements, orally or in writing, to purchase or acquire from the Company any shares of Common Stock or Preferred Stock, or any securities convertible into or exchangeable for shares of Common Stock or Preferred Stock. All outstanding shares of the Company's Common Stock and all shares of the Company's Common Stock underlying outstanding options are subject to (i) a right of first refusal in favor of the Company upon any proposed transfer (other than transfers for estate planning purposes); and (ii) a lock-up or market standoff agreement of not less than one hundred eighty (180) days following the Company's initial public offering pursuant to a registration statement filed with the Securities and Exchange Commission under the Securities Act.

H. **Legends**.

The Undersigned understands that (i) the certificates representing the Shares will have a legends reflecting the restrictions on transfer set forth the Investor Documents and (ii) unless and until the Shares have been registered under the Securities Act and applicable state securities laws the following legend is applicable and each certificate representing such securities shall also bear a legend substantially similar to the following:

> THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.

I. **No Regulatory Approval of Merits**.

The Undersigned understands that neither the Securities and Exchange Commission nor the commissioner or department of securities or attorney general of any state has passed upon the accuracy or adequacy of this Agreement, the fairness of the terms of the offering or the merits or qualifications of, nor recommended nor approved, the Shares. Any representation to the contrary is a criminal offense.

J. **Restrictions on Transfer; Duration**.

The Undersigned shall not, directly or indirectly, sell, transfer, assign, pledge, bequeath, hypothecate, mortgage, grant any proxy with respect to, or in any way encumber or otherwise dispose of, the Shares, except in compliance with this Agreement and the Investor Documents. The Undersigned understands that the Undersigned may not cancel, terminate or revoke this Agreement or any agreement made by the Undersigned hereunder and that this Agreement shall survive the Undersigned's death or disability and shall be binding upon the Undersigned's heirs, executors, administrators, successors and assigns.

K. **Authority and Noncontravention**.

The execution and performance hereof violates no order, judgment, injunction, agreement or controlling document to which the Undersigned is a party or by which the Undersigned is bound. If an organization, (i) the Undersigned is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it has been formed; (ii) the Undersigned has the right and power under its organizational instruments to execute, deliver and perform its obligations hereunder; and (iii) this Agreement has been duly authorized by all necessary action on the part of all officers, directors, partners, stockholders and trustees and will not violate any agreement to which the Undersigned is a party; and (iv) the individual executing and delivering this Agreement has the requisite right, power, capacity and authority to do so on behalf of the organization. The Undersigned has not been organized for the purpose of subscribing for the Shares. If an individual, the Undersigned has all requisite authority and capacity to purchase the Shares, enter into this Agreement and to perform all obligations required to be performed by the Undersigned hereunder.

L. **Miscellaneous**.

1. Notices. Notices required or permitted to be given hereunder shall be in writing and shall be deemed to be sufficiently given when personally delivered or sent by certified mail, return receipt requested, addressed: (i) if to the Company: John Alam, President and CEO, 20 Park Plaza, Suite 424, Boston, MA, 02116 with a copy to Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C., Attention: William C. Hicks, Scott Stanton and Jason McCaffrey, One Financial Center, Boston, MA 02111, or (ii) if to the Undersigned, at the address set forth below, or at such other address as may have been specified by written notice given in accordance with this paragraph.

2. Entire Agreement. This Agreement and the Investor Documents embody the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersede 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 or the Investor Documents may be used to interpret, change or restrict, the express terms and provisions of this Agreement.This is a separate agreement between the Company and the Undersigned. The Company expects to enter into similar agreements with other investors who acquire shares of our Common Stock at or around the time of the Closing. The Company may enter into one or more agreements with other purchasers with other or different provisions than those set forth in this Agreement or which grant specific rights, benefits or privileges that are not made available to the Undersigned.

3. Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the Company and the Undersigned. Notwithstanding the foregoing, the rights set forth in Section L hereof are for the sole benefit of the Company and may be waived by the Company without the consent of the Undersigned.

4. Waivers and Consents. Failure of the Company to exercise any right or remedy under this Agreement or any other agreement between the Company and the Undersigned, or otherwise, or delay by the Company in exercising such right or remedy, will not operate as a waiver thereof. No waiver by the Company will be effective unless and until it is in writing and signed by the Company.

5. Governing Law. This Agreement shall be enforced, governed and construed in all respects in accordance with the laws of the State of Delaware, as such laws are applied by its courts to agreements entered into and to be performed in Delaware as if by and between residents of Delaware, and shall be binding upon the Undersigned, the Undersigned's heirs, estate, legal representatives, successors and assigns and shall inure to the benefit of the Company, its successors and assigns. If any provision of this Agreement is invalid or unenforceable under any applicable statute or rule of law, then such provision shall be deemed inoperative to the extent that it may conflict therewith and shall be deemed modified to conform with such statute or rule of law. Any provision hereof that may prove invalid or unenforceable under any law shall not affect the validity or enforceability of any other provision hereof.

6. Assignability. Neither this Agreement nor any right, remedy, obligation or liability arising hereunder or by reason hereof shall be assignable by either the Company or the Undersigned without the prior written consent of the other party; provided, however, that the Company may assign any of its rights and obligations under this Agreement to any affiliate of or successor in interest to the Company without consent.

7. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed to be an original and all of which together shall be deemed to be one and the same agreement.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, the Undersigned has/have executed this Agreement as of the date first set forth below.

Purchaser:

[_____]

By: _____
Name:
Its: [_____]

Address:

_____

_____

Email: _____

PURCHASE CONFIRMATION

The foregoing Subscription for Shares of the Company is hereby accepted.

YOU HAVE PURCHASED:

[_____]
(Number of Shares)

shares of Common Stock of
EIP Pharma, Inc.,
at U.S. $1.47 per share.

Total Payment: U.S. $[_____]

EIP PHARMA, INC.

By: _____
Name: John Alam
Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, John Alam., MD, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CervoMed Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant'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 the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ John Alam, MD
John Alam, MD
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, William Tanner, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of CervoMed Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant'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 the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ William Tanner, Ph.D.
William Tanner, Ph.D.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of CervoMed Inc. (the "Company") for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Alam, M.D, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ John Alam, M.D
John Alam, M.D
President and Chief Executive Officer (Principal Executive Officer)
November 13, 2023

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of CervoMed Inc. (the "Company") for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William Tanner, Ph.D., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William Tanner, Ph.D.
William Tanner, Ph.D.
Chief Financial Officer (Principal Financial Officer)
November 13, 2023