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 March 31, 2023

☐ **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

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

Delaware	**30-0645032**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

300 East Main Street, Suite 201
Charlottesville, VA 22902
(Address of principal executive offices, including zip code)

(434) 220-0718
(Registrant's telephone number including area code)

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	DFFN	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None

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 and posted 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, 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 ☐
Non-accelerated filer ☒

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 Act).Yes ☐ No ☒

The number of shares of common stock outstanding at May 11, 2023 was 2,040,025 shares.

DIFFUSION PHARMACEUTICALS INC.
FORM 10-Q
MARCH 31, 2023

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Note Regarding Company References and Other Defined Terms

Unless the context otherwise requires, in this Quarterly Report, (i) references to "Diffusion," "the Company," "we," "our," or "us" refer to Diffusion Pharmaceuticals Inc. and its subsidiaries and (ii) references to "common stock" refer to the common stock, par value $0.001 per share, of the Company, and (iii) all share and per share amounts related to our common stock give effect to our 1-for-50 reverse stock split effected April 18, 2022. 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	Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan, as amended
401(k) Plan	Diffusion Pharmaceuticals Inc. 401(k) Defined Contribution Plan
Annual Report	our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 24, 2023
ASC	Accounting Standard Codification of the FASB
Canaccord	Canaccord Genuity LLC, our financial advisor
CRO	contract research organization
EIP	EIP Pharma, Inc., a Delaware corporation
Exchange Act	Securities Exchange Act of 1934, as amended
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
G&A	general and administrative
GAAP	U.S. generally accepted accounting principles
GBM	glioblastoma multiforme brain cancer
Merger	the proposed merger of Merger Sub with and into EIP, with EIP surviving as a wholly-owned subsidiary of the Company, upon the terms and subject to the conditions set forth in the Merger Agreement
Merger Agreement	the Agreement and Plan of Merger, dated as of March 30, 2023, by and among the Company, Merger Sub, and EIP
Merger Sub	Dawn Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of the Company
Nasdaq	Nasdaq Stock Market, LLC
NOL	net operating loss
Preliminary Merger Proxy Statement	our preliminary proxy statement/prospectus/information statement related to a special meeting of our stockholders related to the transactions contemplated by the Merger Agreement, filed with the SEC on May 11, 2023
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
Reverse Stock Split	the reclassification and combination of all shares of our common stock outstanding at a ratio of one-for-50 approved by our stockholders at the Special Meeting and effective April 18, 2022
SEC	U.S. Securities and Exchange Commission
Series C Preferred Stock	the Company's previously outstanding Series C Convertible Preferred Stock, par value $0.001 per share
TSC	trans sodium crocetinate
U.S.	United States

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:

- the approval by our stockholders of the issuance of our common stock in connection with, and the change of control that would be occasioned by, the Merger, the closing of the Merger, including the timing of the Merger, and the approval of the proposal regarding a potential reverse stock split of our common stock as described in the Preliminary Merger Proxy Statement, the likelihood of the satisfaction of the minimum net cash condition as well as the other conditions to the closing of the Merger, the Exchange Ratio (as defined in the Merger Agreement) and relative ownership levels as of the closing of the Merger, including any adjustments thereto related to Diffusion’s net cash balance at closing of the Merger, the expected benefits of and potential value created by the Merger for the stockholders of Diffusion and EIP, and Diffusion’s ability to control and correctly estimate its operating expenses and its expenses associated with the Merger;
- our cash balances following the closing of the Merger, if any;
- our ability to obtain additional financing in the future and continue as a going concern ;
- the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings;
- the success and timing of our clinical and preclinical studies, including our ability to enroll subjects in our future clinical 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 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;
- recently enacted and future legislation related to the healthcare system;
- other regulatory developments in the U.S., E.U., 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; and
- other risks and uncertainties, including those discussed under the heading "Risk Factors" in our Annual Report and elsewhere 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 or incorporated by reference 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 contains certain trademarks, trade names, and service marks of ours, including "DIFFUSIO$_2$N." All other trade names, trademarks, and service marks appearing in this Quarterly Report are, to the knowledge of Diffusion, 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

Diffusion Pharmaceuticals Inc.
Consolidated Balance Sheets
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 14,645,586	$ 10,113,706
Marketable securities	2,991,770	12,408,940
Prepaid expenses, deposits and other current assets	767,530	112,406
Total current assets	$ 18,404,886	$ 22,635,052
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	971,455	1,127,782
Accrued expenses and other current liabilities	1,154,475	1,289,554
Total liabilities	2,125,931	2,417,336
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Common stock, $0.001 par value: 1,000,000,000 shares authorized: 2,040,025 and 2,039,557 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	2,040	2,040
Additional paid-in capital	165,968,961	165,847,590
Accumulated other comprehensive loss	(3,123)	(35,375)
Accumulated deficit	(149,688,923)	(145,596,539)
Total stockholders' equity	16,278,955	20,217,716
Total liabilities and stockholders' equity	$ 18,404,886	$ 22,635,052

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 1,308,589	$ 2,425,898
General and administrative	2,957,691	2,128,552
Loss from operations	4,266,281	4,554,450
Interest income	(173,897)	(27,809)
Net loss	$ (4,092,384)	$ (4,526,641)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (1.95)	$ (2.22)
Weighted average shares outstanding, basic and diluted	2,039,737	2,038,323
Comprehensive loss:		
Net loss	$ (4,092,384)	$ (4,526,641)
Unrealized gain (loss) on marketable securities	32,252	(49,658)
Comprehensive loss	$ (4,060,132)	$ (4,576,299)

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Stockholders' Equity
Three Months Ended March 31, 2021 and 2023
(unaudited)

	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2022	—	$ —	2,038,185	$ 2,038	$164,914,540	$ —	$(130,005,111)	$ 34,911,467
Sale of series C preferred stock to related parties	10,000	5,000	—	—	—	—	—	5,000
Stock-based compensation expense and vesting of restricted stock units	—	—	207	—	278,131	—	—	278,131
Unrealized loss on marketable securities	—	—	—	—	—	(49,658)	—	(49,658)
Net loss	—	—	—	—	—	—	(4,526,641)	(4,526,641)
Balance at March 31, 2022	10,000	$ 5,000	2,038,392	$ 2,038	$165,192,671	$ (49,658)	$(134,531,752)	$ 30,618,299

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2023	2,039,557	$ 2,040	$165,847,590	$ (35,375)	$(145,596,539)	$ 20,217,716
Stock-based compensation expense and vesting of restricted stock units	468	—	121,371	—	—	121,371
Unrealized gain on marketable securities	—	—	—	32,252	—	32,252
Net loss	—	—	—	—	(4,092,384)	(4,092,384)
Balance at March 31, 2023	2,040,025	$ 2,040	$165,968,961	$ (3,123)	$(149,688,923)	$ 16,278,955

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating activities:		
Net loss	$ (4,092,384)	$ (4,526,641)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	121,371	278,131
Amortization of premium and discount on marketable securities	(50,578)	(13,546)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(655,124)	(495,903)
Accounts payable, accrued expenses and other liabilities	(291,405)	28,146
Net cash used in operating activities	(4,968,120)	(4,729,813)
Cash flows used in investing activities:		
Purchases of marketable securities	—	(22,716,415)
Maturities of marketable securities	9,500,000	—
Net cash provided by (used in) investing activities	9,500,000	(22,716,415)
Cash flows provided by financing activities:		
Proceeds from the sale of series C preferred stock to related parties	—	5,000
Net cash provided by financing activities	—	5,000
Net increase (decrease) in cash and cash equivalents	4,531,880	(27,441,228)
Cash and cash equivalents at beginning of period	10,113,706	37,313,558
Cash and cash equivalents at end of period	$ 14,645,586	$ 9,872,330
Supplemental disclosure of non-cash financing activities:		
Unrealized gain (loss) on marketable securities	$ 32,252	$ (49,658)

See accompanying notes to unaudited interim consolidated financial statements.

1. Organization and Description of Business

Diffusion Pharmaceuticals Inc., a Delaware corporation, is a biopharmaceutical company that has historically focused on developing novel therapies that may enhance the body's ability to deliver oxygen to areas where it is needed most. The Company's most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including GBM.

2. Liquidity

The Company has not generated any revenues from product sales and has historically funded operations primarily from the proceeds of public and private offerings of equity, convertible debt, and convertible preferred stock.

In July 2022, the Company entered into an at-the-market sales agreement (the "2022 Sales Agreement") with BTIG pursuant to which the Company may, from time to time and through BTIG as its agent, sell up to an aggregate of $20.0 million in shares of the Company's common stock by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. To date, the Company has not sold any shares pursuant to the 2022 Sales Agreement.

On October 25, 2022, the Company announced that its Board authorized a thorough review and evaluation of a range of potential strategic opportunities in the interest of enhancing stockholder value, including transactional opportunities such as a merger, joint venture, licensing, sale, or divestiture of assets.

In the first quarter of 2023, in connection with the ongoing strategic review process and efforts to utilize and preserve assets in a manner that maximizes value for its stockholders, the Company committed to a reduction in force that impacted seven of the Company's thirteen employees. The reduction was a cash preservation measure and impacted employees primarily in the Company's clinical operations function. In connection with the strategic review process and pending its conclusion, the Company has paused significant portions of its TSC development activities, including initiation of the Company's previously announced Phase 2 study of TSC in newly diagnosed GBM patients.

On March 30, 2023, the Company entered into the Merger Agreement with EIP and Merger Sub, pursuant to which, and subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will be merged with and into EIP at the effective time of the Merger, with EIP continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of the Company. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. As of the date of this Quarterly Report, the Merger remains pending and subject to, among other closing conditions, certain approvals by the Company's stockholders, and there is no assurance in the Merger or any other transaction will be consummated.

Substantial additional financing will be required by the Company to fund any research and development activities related to the Company's existing or future product candidates, including EIP's product candidates if the Merger is closed. The Company regularly explores alternative means of financing its operations and seeks funding through various sources, including public and private securities offerings, collaborative arrangements with third parties, and other strategic alliances and business transactions. However, as of the date of this Quarterly Report, the Company does not have any commitments to obtain additional funds and no assurance can be given that any such financing will be available in the future — when needed, in sufficient amounts, on acceptable terms, or at all. If the Company cannot obtain the necessary funding, it may need to, among other things, delay, continue to scale back or eliminate research and development programs, modify its overall development strategy for one or more product candidates (or the Company as a whole) in a manner it would not if sufficient cash resources were available, or cease operations altogether.

Operations of the Company are subject to certain additional risks and uncertainties as well, and any one or more of these factors could materially affect the Company's financial condition, future operations and liquidity needs. Many of these risks and uncertainties are outside of the Company's control, including the outcome of its ongoing strategic review process and various internal and external factors that may affect the success or failure of the Company's research and development efforts, the length of time and cost of developing and commercializing the Company's current or future product candidates, whether and when any such product candidates become approved drugs, and how significant a drug's market share will be, if approved, among others.

Subject to the outcome and timing of its ongoing strategic review process, and without giving effect to the consummation of the proposed Merger with EIP, the Company currently expect that its existing cash, cash equivalents and marketable securities as of March 31, 2023 are sufficient to fund current operations for at least 12 months following the date of this Quarterly Report.

3. Basis of Presentation and Summary of Significant Accounting Policies

As of the date of this Quarterly Report, the Summary of Significant Accounting Policies included in the Company's Annual Report have not materially changed, except as set forth below.

Basis of Presentation

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with GAAP for interim financial information as found in the ASC and ASUs of the FASB, and with the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the SEC. In the opinion of management, the accompanying unaudited interim consolidated financial statements of the Company include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2023, and its results of operations and cash flows for the three months ended March 31, 2023 and 2022. Operating results for the three months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. The unaudited interim consolidated financial statements presented herein do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2022 filed with the SEC as part of the Annual Report.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

On an ongoing basis, the Company evaluates its estimates using historical experience and other factors, including the current economic environment. Significant items subject to such estimates are assumptions used for purposes of determining stock-based compensation. Management believes its estimates to be reasonable under the circumstances. Actual results could differ significantly from those estimates.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash, cash equivalents, and accounts payable approximate fair value due to the short-term nature of those instruments.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash, cash equivalents, and marketable securities.

Cash and Cash Equivalents

The Company considers any highly-liquid investments, such as money market funds, with an original maturity of three months or less to be cash equivalents.

Marketable securities

The Company classifies its marketable securities as available-for-sale, which include commercial paper and U.S. government debt securities with original maturities of greater than three months from date of purchase. The Company considers its marketable securities as available for use in current operations, and therefore classifies these securities as current assets on the consolidated balance sheet. These securities are carried at fair value, with unrealized gains and losses reported in comprehensive loss and accumulated other comprehensive loss within stockholders' equity. Gains or losses on marketable securities sold will be based on the specific identification method.

The Company routinely monitors the difference between cost and the estimated fair value of its investments. Each reporting period, securities with unrealized losses are reviewed to determine whether the decline in fair value requires the recognition of an allowance for credit losses. Factors considered in the review include (i) current market interest rates, (ii) general financial condition of the issuer, (iii) issuer's industry and future business prospects, (iv) issuer's past defaults in principal and interest payments, and (v) the payment structure of the investment and the issuer's ability to make contractual payments on the investment.

Research and Development

Major components of research and development costs include internal research and development (such as salaries and related employee benefits, equity-based compensation, supplies and allocated facility costs) and contracted services (research and development activities performed on the Company's behalf). Costs incurred for research and development are expensed as incurred.

Upfront payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered.

Patent Costs

Patent costs, including related legal costs, are expensed as incurred and are recorded within general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Stock-based Compensation

The Company measures stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company uses the Black-Scholes Model to value its stock option awards. Estimating the fair value of stock option awards requires management to apply judgment and make estimates, including the volatility of the Company's common stock, the expected term of the Company's stock options, the expected dividend yield and the fair value of the Company's common stock on the measurement date. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

For certain stock option grants, the expected term was estimated using the "simplified method" for employee options as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post vesting employment termination behavior for its stock option grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. The Company uses the simplified method to estimate the expected term.

For stock price volatility, the Company uses a combination of its own historical stock price and comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company's history of not paying dividends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the option. The Company accounts for forfeitures in the periods they occur.

Net Loss Per Common Share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during each period. Diluted net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as common stock warrants, stock options and unvested restricted stock that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

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

	March 31,	
	2023	**2022**
Common stock warrants	88,252	111,891
Stock options	104,047	116,564
Unvested restricted stock awards	2,910	5,182
	195,209	233,637

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses, Measurement of Credit Losses on Financial Instruments* (Topic 326). The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. The Company adopted the guidance using a modified retrospective approach as of January 1, 2023 which resulted in no cumulative-effect adjustment to retained earnings.

The updated guidance in ASU 2016-13 also amended the previous other-than-temporary impairment ("OTTI") model for available-for-sale fixed income securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The Company adopted the guidance related to available-for-sale fixed income securities on January 1, 2023 using a prospective transition approach for available-for-sale fixed income securities that were purchased with credit deterioration or had recognized an OTTI write-down prior to the effective date. The effect of the prospective transition approach was to maintain the same amortized cost basis before and after the effective date.

4. Cash, cash equivalents and marketable securities

The following is a summary of the Company's cash and cash equivalents as of the date indicated:

	March 31, 2023	December 31, 2022
Cash in banking institutions	$ 631,002	$ 1,586,920
Money market funds	14,014,584	8,526,786
Total	$ 14,645,586	$ 10,113,706

The following is a summary of the Company's marketable securities as of as of the date indicated:

	Amortized cost	Unrealized gains	Unrealized losses	Fair Value
March 31, 2023				
Commercial paper	$ 1,995,318	210	$ (1,437)	$ 1,994,091
U.S. treasury bonds	999,575	—	(1,896)	997,679
Total	$ 2,994,893	210	$ (3,333)	$ 2,991,770
December 31, 2022				
Commercial paper	$ 9,445,220	263	$ (21,313)	$ 9,424,170
U.S. treasury bonds	2,999,095	—	(14,325)	2,984,770
Total	$ 12,444,315	263	$ (35,638)	$ 12,408,940

The Company's marketable securities generally have contractual maturity dates between 7 and 30 months.

As of March 31, 2023, $1,991,770 of the marketable securities held were in an unrealized loss position, all of which have been in an unrealized loss position for less than twelve months. The Company determined that unrealized losses on marketable securities were primarily due to market conditions, including changes in the U.S. Federal Reserve interest rate, and not credit losses. The Company does not intend to sell the investments and it is not more likely than not that that the Company will be required to sell the investments before the recovery of the amortized cost basis. No allowance for credit losses related to any of these securities was recorded for the three months ended March 31, 2023.

5. Fair Value of Financial Instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments be made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Company's financial instruments, including prepaid expense and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The Company follows the provisions of FASB ASC Topic 820, *Fair Value Measurement*, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

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

	Fair value measurement at reporting date		
	Quoted prices in active markets for identical assets (Level 1)	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
March 31, 2023			
Cash equivalents:			
Money market funds	$ 14,014,584	$ —	$ —
Commercial paper	—	—	—
Total cash and cash equivalents	$ 14,014,584	$ —	$ —
Marketable securities:			
Commercial paper	—	1,994,090	—
US treasury	—	997,680	—
Total marketable securities	$ —	$ 2,991,770	$ —
Total financial assets	$ 14,014,584	$ 2,991,770	$ —
December 31, 2022:			
Cash equivalents:			
Money market funds	$ 8,526,786	$ —	$ —
Commercial paper	—	—	—
Total cash and cash equivalents	$ 8,526,786	$ —	$ —
Marketable securities:			
Commercial paper	—	9,424,170	—
US treasury	—	2,984,770	—
Total marketable securities	$ —	$ 12,408,940	$ —
Total financial assets	$ 8,526,786	$ 12,408,940	$ —

The fair values of the Company's Level 2 marketable securities are estimated primarily based on benchmark yields, reported trades, market-based quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, and reference data including market research publications, which represent a market approach. In general, a market approach is utilized if there is readily available and relevant market activity for an individual security. This valuation technique may change from period to period, based on the relevance and availability of market data.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of the dates indicated below:

	March 31, 2023	December 31, 2022
Accrued payroll and payroll related expenses	$ 302,085	$ 131,777
Accrued professional fees	734,371	552,785
Accrued clinical studies expenses	16,745	475,141
Other	101,274	129,851
Total	$ 1,154,475	$ 1,289,554

7. Stockholders' Equity and Common Stock Warrants

Common Stock Warrants

As of March 31, 2023, the Company had the following warrants outstanding to acquire shares of its common stock:

	Outstanding	Range of exercise price per share	Expiration dates
Common stock warrants issued related to the May 2019 common stock offering	27,648	$250.09 - $306.04	May and December 2024
Common stock warrants issued related to the November 2019 common stock offering	4,269	$17.51	May 2024
Common stock warrants issued related to the December 2019 common stock offering	6,264	$21.68 - $34.92	December 2024 and June 2025
Common stock warrants issued related to the May 2020 common stock offering	11,424	$65.65	March 2025
Common stock warrants issued related to the May 2020 investor warrant exercise	4,998	$29.7	November 2025
Common stock warrants issued related to the February 2021 common stock offering	33,649	$64.08	February 2026
	88,252		

During the three months ended March 31, 2023, 23,639 warrants expired.

8. Stock-Based Compensation

2015 Equity Plan

The 2015 Equity Plan provides for increases to the number of shares reserved for issuance thereunder each January 1 equal to 4.0% of the total shares of the Company’s common stock outstanding as of the immediately preceding December 31, unless a lesser amount is stipulated by the Compensation Committee of the Company's board of directors. Accordingly, 81,582 shares were added to the reserve as of January 1, 2023, which shares may be issued in connection with the grant of stock-based awards, including stock options, restricted stock, restricted stock units, stock appreciation rights and other types of awards as deemed appropriate, in each case, in accordance with the terms of the 2015 Equity Plan. As of March 31, 2023, there were 141,096 shares available for future issuance under the 2015 Equity Plan.

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

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 12,011	$ 58,892
General and administrative	109,360	219,239
Total stock-based compensation expense	$ 121,371	$ 278,131

The following table summarizes the activity related to all stock option grants for the three months ended March 31, 2023:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Balance at January 1, 2023	140,040	$ 126.75		
Granted	—	—		
Cancelled	(35,993)	20.13		
Outstanding at March 31, 2023	104,047	$ 163.64	7.99	$ —
Exercisable at March 31, 2023	78,533	$ 211.21	7.75	$ —
Vested and expected to vest at March 31, 2023	104,047	$ 163.64	7.99	$ —

There were no options granted during the three months ended March 31, 2023. The total fair value of options vested during the three months ended March 31, 2023 and 2022 was $0.1 million and $0.2 million, respectively. No options were exercised during any of the periods presented. At March 31, 2023, there was $0.4 million of unrecognized compensation expense that will be recognized over a weighted-average period of 1.27 years.

Restricted Stock Unit Awards

The Company issues restricted stock ("RSU") to newly elected, non-executive members of the board of directors that vest in six, tri-monthly installments beginning 18 months after the respective grant date. The fair value of an RSU is equal to the fair market value price of the Company’s common stock on the date of grant. RSU expense is recorded on a straight-line basis over the service period.

The following table summarizes activity related to RSU awards during the period indicated:

	Number of Units	Weighted average grant date fair value
Balance at January 1, 2023	3,652	$ 36.49
Vested (1)	(742)	33.72
Outstanding at March 31, 2023	2,910	$ 38.28

(1) The RSUs vested during the three months ended March 31, 2023 were settled on a hybrid basis. The Company withheld 274 shares of common stock and, in lieu of delivering such shares, paid the RSU holder an amount in cash equal to the fair market value of such shares on the vesting date, representing the holder's approximate tax liability associated with the vesting.

The Company recognized approximately $14,000 and $16,000 in expense related to these awards during the three months ended March 31, 2023 and March 31, 2022, respectively. At March 31, 2023, there was $48,000 in unrecognized compensation cost that will be recognized over a weighted average period of 1.04 years.

9. Commitments and Contingencies

Office Space Lease Commitment

The Company has a short term agreement to utilize membership-based co-working space in Charlottesville, Virginia and was previously party to a second, similar agreement for co-working space in Philadelphia, Pennsylvania, which was terminated during the year ended December 31, 2022. Rent expense related to the Company's short-term agreements was approximately $1,000 and $9,000 for the three months ended March 31, 2023 and 2022, respectively.

Research and Development Arrangements

Prior to the strategic review process and entry into the Merger Agreement with EIP, in the course of normal business operations, the Company entered 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 represent a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Defined Contribution Retirement Plan

The Company has established 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 $26,000 and $27,000 for the three months ended March 31, 2023 and 2022, respectively.

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, following which the parties agreed to stipulate to mediation in advance of the trial. On October 20, 2022, the parties filed a joint stipulation to continue the trial and certain deadlines related to the mediation in order to allow plaintiff's counsel to continue to seek treatment for an ongoing medical issue. On November 1, 2022, based on the parties joint stipulation, the court entered an order continuing the trial date to October 25, 2023.

The Company believes the claims in this matter are without merit and is defending itself vigorously. However, at this stage, the Company is unable to predict the outcome and possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company's financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company's consolidated financial position, results of operations and cash flows.

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

You should read the following discussion of our financial condition and results of operations together with the unaudited interim consolidated financial statements and the notes thereto included elsewhere in this report and other financial information included in this report. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "*Part I — Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Special Note Regarding Forward-Looking Statements*" in this report and under "*Part I — Item 1A. Risk Factors*" in our Annual Report, as well as the risk factors discussed under the heading "*Risk Factors*" in the Preliminary Merger Proxy Statement. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

Diffusion is a biopharmaceutical company that has historically focused on developing novel therapies that may enhance the body's ability to deliver oxygen to the areas where it is needed most. Our most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including hypoxic solid tumors like GBM.

In our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC in March 2022, we identified the pursuit of an opportunistic transaction with the potential to complement and diversify our portfolio of product candidates as one of our key strategic objectives intended to enhance long-term value for our stockholders. In pursuit of this objective, in July 2022, we engaged Canaccord as our financial advisor to support our process and, in October 2022, following further deterioration of the public capital markets throughout 2022 and the corresponding increase in the cost of capital for small biopharmaceutical companies, we publicly announced our board of directors' authorization of an expanded evaluation and review of potential strategic transactions, including a joint venture, licensing, merger, reverse merger, sale or divestiture of some of proprietary technologies or a sale of Diffusion, among others.

On March 30, 2023, Diffusion, Merger Sub and EIP entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into EIP, with EIP surviving the merger as the wholly-owned subsidiary of the combined company. If consummated, immediately following the effective time of the Merger, former EIP stockholders are expected to own approximately 77.26% of the outstanding shares of our common stock, and stockholders of Diffusion as of immediately prior to the effective time of the Merger are expected to own approximately 22.74% of the outstanding shares of our common stock, in each case, as calculated in the Merger Agreement and assuming "Parent Net Cash" (as defined in the Merger Agreement, which is attached as an exhibit to this Quarterly Report) at the closing of the Merger is between $13.5 million and $14.5 million. The actual amount of Parent Net Cash delivered at Closing will depend on many factors, including among others, the date of the closing, and no assurance can be given as to the actual amount of Parent Net Cash that will be delivered.

If the Merger is completed, it will result in a combined company primarily focused on the advancement of central nervous system focused therapeutics, including EIP's lead drug candidate neflamapimod, which is currently being developed for the treatment of dementia with Lewy bodies ("DLB"). Phase 2a clinical trial results with neflamapimod in DLB that showed statistically significant positive effects compared to placebo on dementia severity and walking ability were published in a major scientific journal in September 2022, and in January 2023, EIP was awarded $21.0 million in non-dilutive grant funding from the National Institutes of Health's National Institute on Aging that is expected to fully fund clinical trial costs associated with a planned Phase 2b study evaluating neflamapimod in patients with DLB, a study which EIP anticipates initiating by the end of the second quarter of 2023.

If the Merger is not completed, we will reconsider our strategic alternatives and may pursue one of the following courses of action, which we currently believes are the most likely alternatives if the Merger is not completed:

- *Pursue another strategic transaction similar to the Merger.* We may resume our process of evaluating other companies interested in pursuing a strategic transaction with us and, if a candidate is identified, focus our attention on negotiating and completing such a transaction with such candidate.

- *Dissolve and liquidate its assets,* If we are unable, or do not believe that we will be able, to find a suitable candidate for another strategic transaction in the best interests of our stockholders, we may dissolve and liquidate its assets. In the event of dissolution, we would be required to pay all its debts and contractual obligations and to set aside certain reserves for potential future claims. If we dissolve and liquidate our assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to our stockholders after paying our debts and other obligations and setting aside funds for its reserves.

Subject to the availability of additional funding on acceptable terms, we may also consider resuming development of TSC if the Merger is not completed.

Financial Summary

As of March 31, 2023, we had cash, cash equivalents, and marketable securities of $17.6 million, in the aggregate. We have incurred operating losses since inception, have not generated any product sales revenue and have not achieved profitable operations. We incurred a net loss of $4.1 million for the three months ended March 31, 2023, mostly related to payment of non-recurring severance cost during the period. Our accumulated deficit as of March 31, 2023 was $149.6 million, and we expect to continue to incur substantial losses in future periods.

Currently and during the period ended March 31, 2023, the majority of our costs are and were related to our strategic review process and proposed Merger with EIP. We also expect, if we complete the Merger, another strategic transaction, or resume development of TSC, to continue to incur substantial losses in future periods for the foreseeable future, including any costs related to:

- any additional studies we may undertake to evaluate our current or future product candidates, including other preclinical and clinical studies to support the filing of any NDA with the FDA
- other research, development, and manufacturing activities designed to develop and optimize formulation, manufacturing processes, dosage, dose forms, and other characteristics prior to regulatory approval;
- the maintenance, expansion, and protection our global intellectual property portfolio;
- the hiring of additional clinical, manufacturing, scientific, sales, or other personnel
- research and development related to any other product candidates we may acquire or in-license in the future; and
- investments in operational, financial, and management information systems

Subject to the outcome and timing of our ongoing strategic review process, and without giving effect to the consummation of the proposed Merger with EIP, we currently expect that our existing cash, cash equivalents and marketable securities as of March 31, 2023 are sufficient to fund current operations for at least 12 months following the date of this Quarterly Report.

Additionally, if completed, the Merger will result in an ownership change under Section 382 of the U.S. tax code for Diffusion, and our pre-merger NOL carryforwards and certain other tax attributes will be subject to limitation. Similar rules may apply under state tax laws. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Diffusion's, EIP's, and the combined company's NOL carryforwards and other tax attributes.

Financial Operations Overview

Revenues

We have not yet generated any revenue from product sales. We do not expect to generate revenue from product sales for the foreseeable future.

Research and Development Expense

R&D expenses include, but are not limited to, third-party CRO arrangements and employee-related expenses, including salaries, benefits, stock-based compensation, and travel expense reimbursement. R&D activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical studies.

General and Administrative Expense

G&A expenses consist principally of salaries and related costs for executive and other personnel, including stock-based compensation, other employee benefit costs, expenses associated with investment bank and other financial advisory services, and travel expenses. Other G&A expenses include, facility-related costs, communication expenses and professional fees for legal, patent prosecution and maintenance, consulting, accounting, and other professional services.

Interest Income

Interest income consists of interest earned from our cash, cash equivalents and marketable securities.

Results of Operations for Three Months Ended March 31, 2023 Compared to Three Months Ended March 31, 2022

The following table sets forth our results of operations for the three months ended March 31, 2023 and 2022.

	Three Months Ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 1,308,589	$ 2,425,898	$ (1,117,309)
General and administrative	2,957,691	2,128,552	829,139
Loss from operations	4,266,281	4,554,450	(288,169)
Other income:			
Interest income	(173,897)	(27,809)	(146,088)
Net loss	$ (4,092,384)	$ (4,526,641)	$ 434,257

We recognized $1.3 million in research and development expenses during the three months ended March 31, 2023 compared to $2.4 million during the three months ended March 31, 2022. This decrease was due to lower project spending due to the completion and/or wind-down of certain CMC-related activities and clinical studies evaluating TSC offset by non-recurring severance cost paid during the period.

General and administrative expenses were $3.0 million during the three months ended March 31, 2023 compared to $2.1 million during the three months ended March 31, 2022. The increase was primarily due an increase in professional fees related to ongoing business development activity.

The increase in interest income for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 was primarily as a result of rising interest rates during the first quarter of 2023.

Liquidity and Capital Resources

Working Capital

As of March 31, 2023, we had $14.6 million in cash and cash equivalents, $3.0 million in marketable securities, working capital of $16.4 million and an accumulated deficit of $149.6 million. We expect to continue to incur net losses for the foreseeable future. We intend to use our existing cash, cash equivalents, and marketable securities to fund our working capital and, subject to the completion and outcome of our strategic review process, research and development of our product candidates.

Cash Flows

The following table sets forth our cash flows for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
Net cash provided by (used in):	2023	2022
Operating activities	$ (4,968,120)	$ (4,729,813)
Investing activities	9,500,000	(22,716,415)
Financing activities	—	5,000
Net increase (decrease) in cash and cash equivalents	$ 4,531,880	$ (27,441,228)

Operating Activities

Net cash used in operating activities of $5.0 million during the three months ended March 31, 2023 was primarily attributable to our net loss of $4.1 million and our net change in operating assets and liabilities of $1.1 million. This amount was offset by $0.1 million in stock-based compensation expense. The net change in our operating assets and liabilities is primarily attributable to a decrease in our accrued expenses and other current liabilities due to the timing of our payments to our vendors and employees as well as an increase in our prepaid expenses, deposits, and other current assets.

Net cash used in operating activities of $4.7 million during the three months ended March 31, 2022 was primarily attributable to our net loss of $4.5 million and our net change in operating assets and liabilities of $0.5 million. This amount was offset by $0.3 million in stock-based compensation expense. The net change in our operating assets and liabilities is primarily attributable to an increase in our prepaid expenses, deposits and other current assets.

Investing Activities

During the three months ended March 31, 2023, $9.5 million in marketable securities matured. During the three months ended March 31, 2022, we purchased $22.7 million in marketable securities with cash.

Financing Activities

Net cash provided by financing activities was $5,000 during the three months ended March 31, 2022, attributable to proceeds received from the sale of our Series C Convertible Preferred Stock.

Capital Requirements

Historically, we have incurred substantial expenses and generated significant operating losses pursuing its business strategy of developing TSC. As of the date of this Quarterly Report, most of our cash resources are dedicated to, and its planned expenditures are primarily related to, the Merger.

While we currently believes we have adequate cash resources to fund our current operations for at least 12 months, we anticipate that, if we complete the Merger, another strategic transaction, or resume development of TSC, we will likely need additional funding in the future to support our research and development activities and other operations which, if available, could be obtained through additional capital raising transactions, entry into strategic partnerships or collaborations, or alternative financing arrangements.

In July 2022, we entered into an At-The-Market Sales Agreement, dated July 22, 2022, with BTIG LLC, as agent (the “2022 Sales Agreement”). The 2022 Sales Agreement is an “at-the-market” sales agreement pursuant to which we may, from time to time and through BTIG as our agent, sell up to an aggregate of $20.0 million in shares of common stock by any permissible method deemed an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act. As of the date of this Quarterly Report, however, we have not sold any shares pursuant to the 2022 Sales Agreement.

In the future, we may seek to raise additional funds through various sources. However, we can give no assurances that we will be able to secure additional sources of funds to support its operations, or if such funds are available to us, that such additional financing will be sufficient or be on acceptable terms. This risk may increase if economic and market conditions continue to be challenging or deteriorate. If we are unable to obtain additional financing when needed, we may need to curtail portions of our operations, terminate, significantly modify, or delay the development of our product candidates, or obtain funds on terms that may require us to relinquish rights to our technologies, product candidates or other assets that we might otherwise seek to develop or commercialize independently or receive superior value. If we are unable to raise adequate additional capital as and when required in the future, we could be forced to cease development activities and terminate our operations, and our stockholders could experience a complete loss of their investment.

To the extent that we raise additional capital in the future through the sale of common stock or securities convertible or exchangeable for common stock such as common stock warrants, convertible preferred stock, or convertible debt instruments, or fund acquisitions or other transactions through the issuance of such securities, the interests of our current stockholders may be diluted or otherwise impacted. In particular, specific rights granted to future holders of preferred stock or convertible debt securities may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

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 Policies

As of the date of this Quarterly Report, the Critical Accounting Policies included in our Annual Report have not changed.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, 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-15(e) 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 were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports 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 officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure.

Change in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act) that occurred during the period ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For this item, please refer to *Note 7, Commitments and Contingencies* in the notes accompanying the unaudited interim consolidated financial statements included in Part I, Item 1 of this Quarterly Report, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

As of the date of this Quarterly Report, there have been no material changes to our risk factors previously disclosed in our Annual Report except as disclosed under the heading, "*Risk Factors*" in the Preliminary Merger Proxy Statement.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See attached Exhibit Index.

DIFFUSION PHARMACEUTICALS INC.

QUARTERLY REPORT ON FORM 10-Q
EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
2.1	Agreement and Plan of Merger, dated as of March 30, 2023, by and among Diffusion Pharmaceuticals Inc., EIP Pharma, Inc. and Dawn Merger Sub Inc. (1)	Incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K filed on March 30, 2023
10.1	Form of EIP Pharma, Inc. Stockholder Support Agreement, dated as of March 30, 2023	Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on March 30, 2023
10.2	Form of Lock-Up Agreement, dated as of March 30, 2023	Incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed on March 30, 2023
10.3	Amendment, dated March 29, 2023, to Employment Agreement, dated September 8, 2020, by and between Diffusion Pharmaceuticals Inc. and Robert J. Cobuzzi, Ph.D.	Incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed on March 30, 2023
10.4	Amendment, dated March 29, 2023, to Employment Agreement, dated September 21, 2018, by and between Diffusion Pharmaceuticals Inc. and William Hornung	Incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed on March 30, 2023
10.5	Amendment, dated March 29, 2023, to Employment Agreement, dated September 23, 2020, by and between Diffusion Pharmaceuticals Inc. and William Elder	Incorporated by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed on March 30, 2023
10.6	Separation Agreement and General Release, effective as of March 8, 2023, by and between Diffusion Pharmaceuticals and Christopher D. Galloway, M.D.	Incorporated by reference to Exhibit 10.14 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 24, 2023
10.7	Separation Agreement and General Release, effective as of March 8, 2023, by and between Diffusion Pharmaceuticals and Raven Jaeger	Incorporated by reference to Exhibit 10.15 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 24, 2023
99.1	Form of Diffusion Pharmaceuticals Inc. Stockholder Support Agreement, dated as of March 30, 2023	Incorporated by reference to Exhibit 99.1 to the registrant's current report on Form 8-K filed on March 30, 2023
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of principal financial officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
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	Furnished herewith
101	The following materials from Diffusion's quarterly report on Form 10-Q for the quarter ended March 31, 2023, formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Consolidated Balance Sheets, (ii) the Unaudited Consolidated Statements of Operations, (iii) the Unaudited Consolidated Statement of Changes in Stockholders' Equity, (iv) the Unaudited Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Consolidated Financial Statements	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contaminated in Exhibit 101)	

(1) Schedules and exhibits have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. Diffusion agrees to furnish on a supplemental basis a copy of any omitted schedule or exhibit to the SEC upon its request; provided, however, that Diffusion may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule or exhibit so furnished.

SIGNATURES

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

Date: May 15, 2023

DIFFUSION PHARMACEUTICALS INC.

By: /s/ Robert J. Cobuzzi, Jr., Ph.D.
Robert J. Cobuzzi, Jr., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ William Hornung
William Hornung
Chief Financial Officer
(Principal Financial and Accounting 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, Robert J. Cobuzzi, Jr., Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Diffusion Pharmaceuticals 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: May 15, 2023

/s/ Robert J. Cobuzzi, Jr., Ph.D.
Robert J. Cobuzzi, Jr., Ph.D.
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 K. Hornung, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Diffusion Pharmaceuticals 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: May 15, 2023

/s/ William K. Hornung
William K. Hornung
Chief Financial Officer
(Principal Financial and Accounting 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 Diffusion Pharmaceuticals Inc. (the "Company") for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert J. Cobuzzi, Jr., Ph.D, President and 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/ Robert J. Cobuzzi, Jr., Ph.D
Robert J. Cobuzzi, Jr., Ph.D
President and Chief Executive Officer
May 15, 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 Diffusion Pharmaceuticals Inc. (the "Company") for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. Hornung, 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 K. Hornung
William K. Hornung
Chief Financial Officer (Principal Financial and Accounting Officer)
May 15, 2023