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 June 30, 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 101
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 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 ☐	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 Act).Yes ☐ No ☒

The number of shares of common stock outstanding at August 7, 2023 was 2,040,287 shares.

DIFFUSION PHARMACEUTICALS INC.
FORM 10-Q
JUNE 30, 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. 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
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
Merger Proxy Statement	our proxy statement/prospectus/information statement in connection with the special meeting of our stockholders related to the transactions contemplated by the Merger Agreement, filed with the SEC on July 13, 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 and closing of the Merger, including the timing of the Merger, the ability of Diffusion to obtain a sufficient number of proxies to approve the issuance of common stock in the Merger and the Reverse Split, the likelihood of the satisfaction of other conditions to the closing of the Merger and whether and when the Merger will be consummated, Diffusion's net cash at closing, the Exchange Ratio and relative ownership levels as of the 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 14,999,548	$ 10,113,706
Marketable securities	—	12,408,940
Prepaid expenses, deposits and other current assets	695,070	112,406
Total assets	$ 15,694,618	$ 22,635,052
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	932,427	1,127,782
Accrued expenses and other current liabilities	532,550	1,289,554
Total liabilities	1,464,977	2,417,336
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Common stock, $0.001 par value: 1,000,000,000 shares authorized: 2,040,287 and 2,039,557 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2,040	2,040
Additional paid-in capital	166,029,626	165,847,590
Accumulated other comprehensive loss	—	(35,375)
Accumulated deficit	(151,802,025)	(145,596,539)
Total stockholders' equity	14,229,641	20,217,716
Total liabilities and stockholders' equity	$ 15,694,618	$ 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 72,185	$ 2,108,553	$ 1,380,774	$ 4,534,451
General and administrative	2,220,373	2,137,326	5,178,065	4,265,878
Loss from operations	2,292,558	4,245,879	6,558,839	8,800,329
Interest income	(179,456)	(55,378)	(353,353)	(83,187)
Net loss	$ (2,113,102)	$ (4,190,501)	$ (6,205,486)	$ (8,717,142)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.04)	$ (2.06)	$ (3.04)	$ (4.28)
Weighted average shares outstanding, basic and diluted	2,040,066	2,038,727	2,039,902	2,038,529
Comprehensive loss:				
Net loss	$ (2,113,102)	$ (4,190,501)	$ (6,205,486)	$ (8,717,142)
Unrealized gain (loss) on marketable securities	3,123	(36,925)	35,375	(86,583)
Comprehensive loss:	$ (2,109,979)	$ (4,227,426)	$ (6,170,111)	$ (8,803,725)

See accompanying notes to unaudited interim consolidated financial statements.

Diffusion Pharmaceuticals Inc.
Consolidated Statements of Stockholders' Equity
Three and Six Months Ended June 30, 2022 and 2023
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at April 1, 2023	2,040,025	$ 2,040	$165,968,961	$ (3,123)	$(149,688,923)	$ 16,278,955
Stock-based compensation expense and vesting of restricted stock units	262	—	60,665	—	—	60,665
Unrealized gain on marketable securities	—	—	—	3,123	—	3,123
Net loss	—	—	—	—	(2,113,102)	(2,113,102)
Balance at June 30, 2023	2,040,287	$ 2,040	$166,029,626	$ —	$(151,802,025)	$ 14,229,641

	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	730	—	182,036	—	—	182,036
Unrealized gain on marketable securities	—	—	—	35,375	—	35,375
Net loss	—	—	—	—	(6,205,486)	(6,205,486)
Balance at June 30, 2023	2,040,287	$ 2,040	$166,029,626	$ —	$(151,802,025)	$ 14,229,641

	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 April 1, 2022	10,000	$ 5,000	2,038,392	$ 2,038	$165,192,671	$ (49,658)	$(134,531,752)	$ 30,618,299
Conversion of Series C preferred stock to common stock	(10,000)	(5,000)	200	—	5,000	—	—	—
Stock-based compensation expense and vesting of restricted stock units	—	—	322	—	278,130	—	—	278,130
Unrealized loss on marketable securities	—	—	—	—	—	(36,925)	—	(36,925)
Net loss	—	—	—	—	—	—	(4,190,501)	(4,190,501)
Balance at June 30, 2022	—	$ —	2,038,914	$ 2,038	$165,475,801	$ (86,583)	$(138,722,253)	$ 26,669,003

	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2022	—	$ —	2,038,185	$ 2,038	$164,914,540	$ —	$ (130,005,111)	$ 34,911,467
Sale of Series C preferred stock to related parties	10,000	5,000	—	—	—	—	—	5,000
Conversion of Series C preferred stock to common stock	(10,000)	(5,000)	200	—	5,000	—	—	—
Stock-based compensation expense and vesting of restricted stock units	—	—	529	—	556,261	—	—	556,261
Unrealized loss on marketable securities	—	—	—	—	—	(86,583)	—	(86,583)
Net loss	—	—	—	—	—	—	(8,717,142)	(8,717,142)
Balance at June 30, 2022	—	$ —	2,038,914	$ 2,038	$165,475,801	$ (86,583)	$(138,722,253)	$ 26,669,003

See accompanying notes to unaudited interim consolidated financial statements.

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

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (6,205,486)	$ (8,717,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	182,036	556,261
Amortization of premium and discount on marketable securities	(55,685)	(45,439)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(582,664)	(118,025)
Accounts payable, accrued expenses and other liabilities	(952,359)	(412,662)
Net cash from operating activities	(7,614,158)	(8,737,007)
Cash flows from investing activities:		
Purchase of marketable securities	—	(31,615,825)
Maturities of marketable securities	12,500,000	9,000,000
Net cash used in investing activities	12,500,000	(22,615,825)
Cash flows from financing activities:		
Proceeds from the sale of preferred stock	—	5,000
Net cash provided by financing activities	—	5,000
Net increase (decrease) in cash and cash equivalents	4,885,842	(31,347,832)
Cash and cash equivalents at beginning of period	10,113,706	37,313,558
Cash and cash equivalents at end of period	$ 14,999,548	$ 5,965,726
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized loss on marketable securities	$ —	$ (86,583)

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, most recently as an adjuvant treatment to standard of care therapy for GBM and other hypoxic solid tumors. 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. Diffusion has called a special meeting of stockholders currently scheduled for August 15, 2023 in order to obtain the stockholder approvals necessary to complete the Merger and certain related transactions, as more fully described in the Merger Proxy Statement.

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.

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. Diffusion has called a special meeting of stockholders currently scheduled for August 15, 2023 in order to obtain the stockholder approvals necessary to complete the Merger and certain related transactions, as more fully described in the Merger Proxy Statement. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. In connection with the Merger Agreement with EIP and efforts to utilize and preserve assets in a manner that maximizes value for its stockholders, the Company committed to a reduction in force in the first quarter of 2023 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. The Company has paused significant portions of its TSC development activities in the first quarter of 2023, including initiation of the Company's previously announced Phase 2 study of TSC in newly diagnosed GBM patients.

Substantial additional financing will be required by the Company to fund any research and development activities related to the Company's existing or future product candidates, 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 pending merger with EIP 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.

Without giving effect to the consummation of the proposed Merger with EIP, the Company currently expect that its existing cash and cash equivalents as of June 30, 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.

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 June 30, 2023, and its results of operations for the three and six months ended June 30, 2023 and 2022 and cash flows for the six months ended June 30, 2023 and 2022. Operating results for the six months ended June 30, 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 on Form 10-K.

Use of Estimates

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

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

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash, cash equivalents, 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 are 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) issuers industry and future business prospects, (iv) issuers past defaults in principal and interest payments, and (v) the payment structure of the investment and the issuers ability to make contractual payments on the investment. All of the Company's marketable securities were fully matured at June 30, 2023.

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 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 in which 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:

	June 30,	
	2023	**2022**
Common stock warrants	88,252	111,891
Stock options	85,961	122,882
Unvested restricted stock awards	2,495	4,672
	176,708	239,445

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:

	June 30, 2023	December 31, 2022
Cash in banking institutions	$ 1,316,052	$ 1,586,920
Money market funds	13,683,496	8,526,786
Total	$ 14,999,548	$ 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
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 had no marketable securities as of June 30, 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)
June 30, 2023			
Cash equivalents:			
Money market funds	$ 13,683,496	$ —	$ —
Total cash equivalents	$ 13,683,496	$ —	$ —
December 31, 2022:			
Cash equivalents:			
Money market funds	$ 8,526,786	$ —	$ —
Commercial paper	—	—	—
Total 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:

	June 30, 2023	December 31, 2022
Accrued payroll and payroll related expenses	$ 265,382	$ 131,777
Accrued professional fees	208,900	552,785
Accrued clinical studies expenses	—	475,141
Other	58,268	129,851
Total	$ 532,550	$ 1,289,554

7. Stockholders' Equity and Common Stock Warrants

Common Stock Warrants

As of June 30, 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 six months ended June 30, 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 June 30, 2023, there were 160,254 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ —	$ 58,892	$ 12,011	$ 117,785
General and administrative	60,665	219,238	170,025	438,476
Total stock-based compensation expense	$ 60,665	$ 278,130	$ 182,036	$ 556,261

The following table summarizes the activity related to all stock option grants for the six months ended June 30, 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	(54,079)	22.04		
Outstanding at June 30, 2023	85,961	$ 192.65	7.65	$ —
Exercisable at June 30, 2023	68,344	$ 238.46	7.42	$ —
Vested and expected to vest at June 30, 2023	85,961	$ 192.65	7.65	$ —

There were no options granted during the six months ended June 30, 2023. The total fair value of options vested during the three months ended June 30, 2023 and 2022 was $0.1 million and $0.3 million, respectively. The total fair value of options vested during the six months ended June 30, 2023 and 2022 was $0.2 million and $0.5 million, respectively. No options were exercised during any of the periods presented. At June 30, 2023, there was $0.2 million of unrecognized compensation expense that will be recognized over a weighted-average period of 1.12 years.

Restricted Stock Unit Awards

The Company previously issued restricted stock units (each, an "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, 2022	3,652	$ 36.49
Vested (1)	(1,157)	36.04
Outstanding at June 30, 2023	2,495	$ 37.57

(1) The RSUs vested during the six months ended June 30, 2023 were settled on a hybrid basis. The Company withheld 512 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 an insignificant amount in expense related to these awards and $16,000 in expense related to these awards during the three months ended June 30, 2023 and June 30, 2022, respectively. The Company recognized an insignificant amount and $32,000 in expense related to these awards during the six months ended June 30, 2023 and 2022, respectively. At June 30, 2023, there was $19,000 in unrecognized compensation cost that will be recognized over a weighted average period of 0.88 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 $2,000 for the three months ended June 30, 2023 and 2022, respectively. Rent expense related to the Company's short-term agreements was approximately $2,000 and $11,000 for the six months ended June 30, 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 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.

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 $10,000 and $26,000 for the three months ended June 30, 2023 and 2022, respectively. The Company made matching contributions under the 401(k) Plan of approximately $35,000 and $53,000 for the six months ended June 30, 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, and the parties have agreed to stipulate to mediation in advance of the trial. On October 20, 2022, the parties filed a joint stipulation to continue the trial and certain deadlines related to the mediation in order to allow plaintiff's counsel to continue to seek treatment for an ongoing medical issue. On November 1, 2022, based on the parties joint stipulation, the court entered an order continuing the trial date to October 25, 2023.

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

Following announcement of the Merger Agreement with EIP and the initial filing on May 11, 2023 of the Company's Registration Statement on Form S-4 (File No. 333-271823) (the "Registration Statement"), two lawsuits were filed in the United States District Court for the Southern District of New York on May 15, 2023 and May 17, 2023, respectively, by purported stockholders of the Company in connection with the Merger. The lawsuits are captioned Dunlea v. Diffusion Pharmaceuticals, Inc., et al., No. 1:23-cv-04043 (S.D.N.Y.) and Pikazin v. Diffusion Pharmaceuticals, Inc., et al., No. 1:23-cv-04096 (S.D.N.Y.). Additional stockholder litigations were subsequently filed in the United States District Courts for the Southern District of New York and the District of Delaware and in the Delaware Court of Chancery (collectively with the first two cases, the "Actions"). The complaints in each of the Actions named as defendants the Company and the members of the Company's board of directors as of such dates. Each of the federal court complaints alleges claims for violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder against all defendants, and violations of Section 20(a) of the Exchange Act against such members of the Company's board of directors. The Chancery Court complaint, filed after the stockholder had received copies of certain documents in response to a books and records demand under Section 220 of the Delaware General Corporation Law, alleges a claim for breach of fiduciary duty. The plaintiff in the Chancery Court action also sought expedited treatment and a preliminary injunction barring the scheduled stockholder vote, but those motions were subsequently withdrawn. The plaintiffs in each of the Actions contend that Registration Statement omitted or misrepresented material information regarding the proposed Merger, rendering the Registration Statement materially misleading. The Actions seek injunctive and declaratory relief, as well as damages. The Company has also received correspondence from law firms claiming to represent other purported stockholders making similar demands for additional disclosures relating to the Merger.

The Company believes that the claims asserted in the Actions and the demand letters are without merit.

Stockholders may serve additional demands and/or file additional lawsuits challenging the Merger, which may name the Company, EIP, members of the Company's 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 additional demands, lawsuits, demand letters or the Actions, 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 additional demands are served and/or any additional lawsuits filed, absent new or different allegations that are material, the Company will not necessarily announce such additional demands and/or complaints, except as required by applicable law including the rules and regulations of the SEC.

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 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 areas where it is needed most. Diffusion's most advanced product candidate, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, most recently as an adjuvant treatment to standard of care therapy for GBM and other hypoxic solid tumors.

Pending Merger with EIP Pharma, Inc

Following an extensive process of evaluating strategic alternatives, on March 30, 2023, we entered into the Merger Agreement with EIP and Merger Sub pursuant to which, among other things, and subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will merge with and into EIP, with EIP continuing as our wholly-owned subsidiary. In connection with the Merger and as more fully described in the Merger Proxy Statement, at a special meeting of stockholders currently scheduled for August 15, 2023, we are seeking approval of our stockholders to, among other things, (a) issue the shares of our common stock issuable to former EIP equity holders in connection with the Merger in accordance with the rules of Nasdaq and (b) amend our certificate of incorporation to effect a reverse stock split of the outstanding shares of our common stock at a ratio of not less than 1-for-1.5 and not more than 1-for-8, if necessary to satisfy applicable Nasdaq listing requirements (clauses (a) and (b), collectively, the "Diffusion Special Meeting Proposals"). Our board of directors unanimously approved the Merger Agreement and unanimously recommended that our stockholders approve the Diffusion Special Meeting Proposals.

If our stockholders approve the Diffusion Special Meeting Proposals and the Merger is completed, at or following the effective time of the Merger, (i) Diffusion will be renamed "CervoMed Inc.," (ii) subject to satisfying Nasdaq's initial listing standards, our common stock's ticker symbol on the Nasdaq Capital Market will change from "DFFN" to "CRVO," and (iii) the combined company will focus on developing EIP's product candidates for acute and chronic neurodegenerative diseases and other neurologic indications. EIP's lead drug candidate, neflamapimod, is currently being developed for the treatment of dementia with Lewy bodies ("DLB"). In the second quarter of 2023, EIP initiated its ongoing, 160-subject Phase 2b clinical trial evaluating neflamapimod in patients with DLB, the clinical trial costs of which are expected to be fully funded by $21.0 million in non-dilutive grant funding from the National Institutes of Health's National Institute on Aging awarded to EIP in January 2023. An initial data readout from the study is anticipated in the second half of 2024.

If consummated, immediately following the effective time of the Merger, Diffusion stockholders as of immediately before the Merger are expected to own approximately 24.68% of the outstanding shares of our common stock and former EIP equity holders as of immediately before the Merger are expected to own approximately 75.32% of the outstanding shares of our common stock, subject to certain assumptions more fully described in the Merger Proxy Statement, including (i) that "Parent Net Cash" (as calculated in accordance with the Merger Agreement) at the closing of the Merger is between $13.5 million and $14.5 million and (ii) the exclusion of an estimated 705,571 shares underlying pre-funded warrants that may be issued to former EIP equity holders at the effective time of the Merger in lieu of an equivalent number of shares of our common stock.

As more fully described in the Merger Proxy Statement, consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval of the Diffusion Special Meeting Proposals by our stockholders, (b) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, and (c) our having Parent Net Cash (as defined in the Merger Agreement) as of closing of the Merger greater than or equal to $12.0 million. The Merger Agreement also contains certain termination rights of each of us and EIP which, in certain circumstances, may result in our being required to pay EIP a termination fee of up to $765,000.

As of June 30, 2023, we had cash and cash equivalents of approximately $15.0 million. However, as set forth in the Merger Agreement and more fully described in the Merger Proxy Statement, the calculation of "Parent Net Cash" involves numerous adjustments to the amount of cash, cash equivalents and marketable securities as reported on our balance sheet and the actual amount of Parent Net Cash delivered at Closing will depend on many factors, including among others, the date of the closing and the magnitude of such adjustments. No assurance can be given as to the actual amount of Parent Net Cash that will be delivered, that our stockholders will approve the Diffusion Special Meeting Proposals, that any other condition to closing will not fail to be satisfied or waived, or that the Merger will be consummated at all. The Company expects to continue to incur losses following the period of this Quarterly Report through the closing of the Merger (if any) primarily related to the proposed Merger and, as a result, available cash, cash equivalents and marketable securities will continue to decrease.

As previously announced, in connection with our strategic review process, the pending Merger with EIP, and our expectation that the combined company will not continue to develop Diffusion's existing assets (other than the potential continuation of efforts to identify third parties that may be interested in a license or other similar transaction involving our TSC assets), we have paused development activity related to TSC including the initiation of our previously announced Phase 2 study in newly diagnosed GBM patients. Accordingly, our future operations are highly dependent on the success of the Merger. In the event that we do not complete the Merger with EIP, we will reconsider our strategic alternatives and may (i) pursue another strategic transaction similar to the Merger or (ii) dissolve and liquidate our assets, which we currently believe are the most likely alternatives if the Merger is not completed. 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 June 30, 2023, we had cash and cash equivalents of approximately $15.0 million. 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 $2.1 million for the three months ended June 30, 2023, mostly related to payment of non-recurring severance cost and an increase in professional fees related to the proposal Merger with EIP during the period. Our accumulated deficit as of June 30, 2023 was $151.8 million, and we expect to continue to incur substantial losses in future periods.

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:

- our strategic review process and proposed Merger with EIP;
- 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

Without giving effect to the consummation of the proposed Merger with EIP, we currently expect that our existing cash and cash equivalents as of June 30, 2023 are sufficient to fund current operations for at least 12 months following the date of this Quarterly Report.

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 June 30, 2023 Compared to Three Months Ended June 30, 2022

The following table sets forth our results of operations for the three months ended June 30, 2023 and 2022.

	Three Months Ended June 30,		
	2023	**2022**	**Change**
Operating expenses:			
Research and development	$ 72,185	$ 2,108,553	$ (2,036,368)
General and administrative	2,220,373	2,137,326	83,047
Loss from operations	(2,292,558)	(4,245,879)	1,953,321
Other income:			
Interest income	179,456	55,378	124,078
Net loss	$ (2,113,102)	$ (4,190,501)	$ 2,077,399

We recognized $0.1 million in research and development expenses during the three months ended June 30, 2023 compared to $2.1 million during the three months ended June 30, 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.

General and administrative expenses were $2.2 million during the three months ended June 30, 2023 compared to $2.1 million during the three months ended June 30, 2022. The increase was primarily due to an increase in professional fees related to the Merger as well as severance cost paid during the period.

The increase in interest income for the three months ended June 30, 2023 compared to the three months ended June 30, 2022 was primarily as a result of rising interest rates during 2023.

Results of Operations for Six Months Ended June 30, 2023 Compared to Six Months Ended June 30, 2022

The following table sets forth our results of operations for the six months ended June 30, 2023, and 2022.

	Six Months Ended June 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 1,380,774	$ 4,534,451	$ (3,153,677)
General and administrative	5,178,065	4,265,878	912,187
Loss from operations	(6,558,839)	(8,800,329)	2,241,490
Other income:			
Interest income	353,353	83,187	270,166
Net loss	$ (6,205,486)	$ (8,717,142)	$ 2,511,656

We recognized $1.4 million in research and development expenses during the six months ended June 30, 2023 compared to $4.5 million during the six months ended June 30, 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 $5.2 million during the six months ended June 30, 2023 compared to $4.3 million during the six months ended June 30, 2022. The increase was primarily due an increase in professional fees related to the Merger as well as severance cost paid during the period.

The increase in interest income for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 was primarily as a result of rising interest rates during 2023.

Liquidity and Capital Resources

Working Capital

As of June 30, 2023, we had $15.0 million in cash and cash equivalents, working capital of $14.2 million and an accumulated deficit of $151.8 million. We expect to continue to incur net losses for the foreseeable future. We intend to use our existing cash and cash equivalents to fund our working capital, cover expenditures related to the Merger, 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 six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,	
Net cash provided by (used in):	2023	2022
Operating activities	$ (7,614,158)	$ (8,737,007)
Investing activities	12,500,000	(22,615,825)
Financing activities	—	5,000
Net increase (decrease) in cash and cash equivalents	$ 4,885,842	$ (31,347,832)

Operating Activities

Net cash used in operating activities of $7.6 million during the six months ended June 30, 2023 was primarily attributable to our net loss of $6.2 million and our net change in operating assets and liabilities of $1.5 million. This amount was offset by $0.2 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 $8.7 million during the six months ended June 30, 2022 was primarily attributable to our net loss of $8.7 million and our net change in operating assets and liabilities of $0.5 million. This amount was offset by $0.6 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.

Investing Activities

During the six months ended June 30, 2023, $12.5 million in marketable securities matured. During the six months ended June 30, 2022, we purchased $31.6 million of marketable securities and $9.0 million of marketable securities matured.

Financing Activities

Net cash provided by financing activities was $5,000 during the six months ended June 30, 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 on Form 10-K 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 June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For this item, please refer to *Note 9, 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 headings, "*Risk Factors -- Risks Related to the Merger,*" beginning on page 37 of the Merger Proxy Statement, "*Risk Factors -- Risks Related to the Reverse Stock Split Proposal*," beginning on page 46 of the Merger Proxy Statement, and "*Risk Factors -- Risks Related to Diffusion,*" beginning on page 48 of the Merger Proxy Statement, which are incorporated herein by reference.

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

10b5-1 Disclosure

None of the officers or directors of the Company have adopted or terminated any Rule 10b5-1 trading arrangements applicable to them (if any) or the Company during the period of this Quarterly Report.

ITEM 6. EXHIBITS

See attached Exhibit Index.

DIFFUSION PHARMACEUTICALS INC.

QUARTERLY REPORT ON FORM 10-Q
EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
10.1	Separation Agreement and General Release, dated May 15, 2023, by and between Diffusion Pharmaceuticals Inc. and William K. Hornung	Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on May 19, 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 June 30, 2023, formatted in inline 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)	

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: August 8, 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 Elder
William Elder
General Counsel and Corporate Secretary
(Principal Financial 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: August 8, 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 Elder, 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: August 8, 2023

/s/ William Elder
William Elder
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 Diffusion Pharmaceuticals Inc. (the "Company") for the quarter ended June 30, 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
August 8, 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 June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William Elder, Principal 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 Elder
William Elder
Principal Financial Officer
August 8, 2023