

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2024

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

For the transition period from _____ to _____.

Commission file number: 001-37942



CervoMed Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

30-0645032

(I.R.S. Employer Identification No.)

20 Park Plaza, Suite 424

Boston, Massachusetts

(Address of principal executive offices)

02116

(Zip Code)

(617) 744-4400

(Registrant's telephone number including area code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 November 7, 2024 was 8,253,741 shares.

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INTRODUCTORY NOTES

Note Regarding Company References and Other Defined Terms

As previously disclosed in our Current Report on Form 8-K filed with the SEC on August 17, 2023, on August 16, 2023, the Delaware corporation formerly known as “Diffusion Pharmaceuticals Inc.” completed a merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger, dated March 30, 2023 (the “Merger Agreement”) by and among Diffusion Pharmaceuticals Inc. (“Diffusion”), Dawn Merger Sub Inc., a wholly-owned subsidiary of Diffusion (“Merger Sub”), and EIP Pharma, Inc. (“EIP”), pursuant to which Merger Sub merged with and into EIP, with EIP surviving the Merger as a wholly-owned subsidiary of Diffusion (the “Merger”). At the Effective Time (as defined below), each outstanding share of EIP capital stock was converted into the right to receive 0.1151 shares of the Company’s common stock and, immediately following the Effective Time, Diffusion changed its name from “Diffusion Pharmaceuticals Inc.” to “CervoMed Inc.”

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

Accordingly, unless the context otherwise requires, all references in this Quarterly Report to (i) “CervoMed,” the “Company,” “we,” “our,” or “us,” refer to the business of EIP for all dates and periods prior to August 16, 2023 and to the business of CervoMed for all dates and periods subsequent to (and including) August 16, 2023 and (ii) “common stock” refers to the common stock, par value \$0.001 per share, of the Company. Historical share and per share figures of EIP have been retroactively restated based upon the Exchange Ratio of 0.1151.

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

Term	Definition
2015 Equity Plan	CervoMed Inc. 2015 Equity Incentive Plan, as amended
2018 Plan	CervoMed Inc. 2018 Employee, Director and Consultant Equity Incentive Plan, as amended
2020 Notes	the previously outstanding convertible promissory notes of EIP, dated as of December 4, 2020, as amended
2021 Notes	the previously outstanding convertible promissory notes of EIP, dated as of December 10, 2021, as amended
2022 Sales Agreement	our At-The-Market Sales Agreement, dated July 22, 2022, with BTIG, as agent, which was terminated in October 2024
2024 Private Placement	our private placement of an aggregate of 2,532,285 units, each consisting of (i) (A) one share of common stock or (B) one Pre-Funded Warrant in lieu thereof and (ii) one Series A Warrant, for aggregate gross proceeds of up to approximately \$149.4 million, completed on April 1, 2024
401(k) Plan	CervoMed Inc. 401(k) Defined Contribution Plan
Annual Report	our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 29, 2024
ASC	Accounting Standard Codification of the FASB
AscenD-LB Trial	our Phase 2a clinical trial evaluating neflmapimod for the treatment of patients with DLB, completed in the second half of 2021
ASU	Accounting Standards Update
BID	twice daily
BFC	basal forebrain cholinergic

Board	the board of directors of the Company
BTIG	BTIG LLC
CDR-SB	Clinical Dementia Rating Sum of Boxes test
CMO	contract manufacturing organization
CNS	central nervous system
Code	the U.S. Internal Revenue Code of 1986, as amended
Convertible Notes	collectively, the 2020 Notes and the 2021 Notes
CRO	contract research organization
DLB	dementia with Lewy bodies
Early-Stage DLB	DLB which has not progressed to a point where the patient has imaging or biomarker evidence of tau pathology or neuronal loss in the medial temporal lobe
Effective Time	the effective time of the Merger on August 16, 2023
EIP Common Stock	the common stock, par value \$0.001, of EIP issued and outstanding prior to the Merger
Exchange Act	Securities Exchange Act of 1934, as amended
Exchange Ratio	the “Exchange Ratio” as defined in the Merger Agreement
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
FTD	frontotemporal dementia
G&A	general and administrative
MoCA	the Montreal Cognitive Assessment
Nasdaq	Nasdaq Stock Market, LLC
NIA	the National Institute on Aging of the National Institutes of Health
NIA Grant	the \$21.3 million grant awarded to us by the NIA to support the RewinD-LB Trial, \$21.0 million of which was awarded in January 2023 and an additional \$0.3 million of which was awarded in August 2024
NIH	National Institutes of Health
NOL	net operating loss
p38 α	p38 mitogen-activated protein kinase alpha
Pre-Funded Warrants	the pre-funded warrants each to purchase one share of common stock at a purchase price of \$0.001 per share issued in connection with the 2024 Private Placement
ptau181	plasma phosphorylated tau at position 181
R&D	research and development
Regulation S-K	Regulation S-K promulgated under the Securities Act
RestorGenex	RestorGenex Corporation, a legal predecessor to the Company prior to a reverse merger transaction consummated in January 2016
RewinD-LB Trial	our Phase 2b clinical trial evaluating neflamapimod for the treatment of patients with Early-Stage DLB initiated in the second quarter of 2023
ROU	right-of-use
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933, as amended
Series A Warrants	the warrants to purchase an aggregate of 2,532,285 shares of common stock at a purchase price of \$39.24 per share issued in connection with the 2024 Private Placement
TID	three times daily
TUG	Timed Up and Go test
U.S.	United States of America
US GAAP	U.S. generally accepted accounting principles
Vertex	Vertex Pharmaceuticals Incorporated
Vertex Agreement	the Option and License Agreement, dated as of August 27, 2012, by and between EIP Pharma LLC and Vertex, as amended

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,” “aims,” “seeks,” “intends,” “may,” “might,” “could,” “will,” “should,” “approximately,” “potential,” “target,” “project,” “contemplate,” “predict,” “forecast,” “continue,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements also include statements regarding our intentions, beliefs, projections, outlook, analyses or expectations concerning, among other things:

- our cash balances and our ability to obtain additional financing in the future;
- the success and timing of our ongoing RewinD-LB Trial and our other clinical and preclinical studies, including our ability to enroll subjects in our studies at anticipated rates and our ability to manufacture an adequate amount of drug supply for our studies;
- obtaining and maintaining intellectual property protection for our current or future product candidates and our proprietary technology;
- the performance of third parties, including contract research organizations, manufacturers, suppliers, and outside consultants, to whom we outsource certain operational, staff and other functions;
- our ability to obtain and maintain regulatory approval of our current or future product candidates and, if approved, our products, including the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our current or future product candidates and the outcomes of our research and development activities;
- our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- our future obligations under the Vertex Agreement;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the accuracy of our estimates of the size and characteristics of the potential markets for our current or future product candidates, the rate and degree of market acceptance of any of our current or future product candidates that may be approved in the future, and our ability to serve those markets;
- the success of products that are or may become available which also target the potential markets for our current or future product candidates;
- our ability to operate our business without infringing the intellectual property rights of others and the potential for others to infringe upon our intellectual property rights;
- any significant breakdown, infiltration, or interruption of our information technology systems and infrastructure;
- our ability to remediate our previously disclosed material weaknesses in our internal controls over financial reporting in a timely manner;

- recently enacted and future legislation related to the healthcare system;
- other regulatory developments in the U.S., European Union, and other foreign jurisdictions;
- our ability to satisfy the continued listing requirements of the Nasdaq 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" herein and in our other public filings.

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

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

Note Regarding Trademarks, Trade Names, and Service Marks

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

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CervoMed Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,743,667	\$ 7,792,846
Marketable securities	38,913,236	—
Prepaid expenses and other current assets	1,888,879	1,256,501
Grant receivable	264,148	915,404
Total current assets	48,809,930	9,964,751
Other assets	73,937	7,770
Total assets	\$ 48,883,867	\$ 9,972,521
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,082,435	\$ 662,471
Accrued expenses and other current liabilities	2,163,936	1,933,276
Total liabilities	3,246,371	2,595,747
Commitments and Contingencies (Note 10)		
Stockholders' Equity:		
Common stock, \$0.001 par value: 1,000,000,000 shares authorized: 8,253,741 and 5,674,520 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	8,253	5,674
Additional paid-in capital	109,531,651	61,811,889
Accumulated other comprehensive income	123,162	—
Accumulated deficit	(64,025,570)	(54,440,789)
Total stockholders' equity	45,637,496	7,376,774
Total liabilities and stockholders' equity	\$ 48,883,867	\$ 9,972,521

See accompanying notes to unaudited condensed consolidated interim financial statements

CervoMed Inc.
Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Grant revenue	\$ 1,939,751	\$ 1,526,482	\$ 7,575,972	\$ 4,654,294
Operating expenses:				
Research and development	5,125,097	1,791,487	11,711,746	5,583,149
General and administrative	2,210,927	2,410,124	6,850,536	4,403,590
Total operating expenses	<u>7,336,024</u>	<u>4,201,611</u>	<u>18,562,282</u>	<u>9,986,739</u>
Loss from operations	(5,396,273)	(2,675,129)	(10,986,310)	(5,332,445)
Other income (expense):				
Other income (expense)	(3,440)	4,777,824	(3,717)	5,422,192
Interest income	646,172	47,667	1,405,246	100,778
Total other income, net	<u>642,732</u>	<u>4,825,491</u>	<u>1,401,529</u>	<u>5,522,970</u>
Net (loss) income	<u>\$ (4,753,541)</u>	<u>\$ 2,150,362</u>	<u>\$ (9,584,781)</u>	<u>\$ 190,525</u>
Per share information:				
Net (loss) income per share of common stock, basic	<u>\$ (0.55)</u>	<u>\$ 0.65</u>	<u>\$ (1.22)</u>	<u>\$ 0.13</u>
Weighted average shares outstanding, basic	<u>8,702,764</u>	<u>3,308,302</u>	<u>7,861,757</u>	<u>1,458,415</u>
Net loss per share of common stock, diluted	<u>\$ (0.55)</u>	<u>\$ (0.70)</u>	<u>\$ (1.22)</u>	<u>\$ (2.37)</u>
Weighted average shares outstanding, diluted	<u>8,702,764</u>	<u>3,766,700</u>	<u>7,861,757</u>	<u>2,209,407</u>
Comprehensive (loss) income:				
Net unrealized gain on marketable securities	142,864	—	123,162	—
Total comprehensive (loss) income	<u>\$ (4,610,677)</u>	<u>\$ 2,150,362</u>	<u>\$ (9,461,619)</u>	<u>\$ 190,525</u>

See accompanying notes to unaudited condensed consolidated interim financial statements

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

Three Month Period Ended September 30, 2024								
	Convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated other comprehensive (loss) income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at June 30, 2024	—	\$ —	8,253,741	\$ 8,253	\$ 109,260,436	\$ (19,702)	\$ (59,272,029)	\$ 49,976,958
Stock-based compensation expense	—	—	—	—	271,215	—	—	271,215
Unrealized gain on marketable securities	—	—	—	—	—	142,864	—	142,864
Net loss	—	—	—	—	—	—	(4,753,541)	(4,753,541)
Balance at September 30, 2024	<u>—</u>	<u>\$ —</u>	<u>8,253,741</u>	<u>\$ 8,253</u>	<u>\$ 109,531,651</u>	<u>\$ 123,162</u>	<u>\$ (64,025,570)</u>	<u>\$ 45,637,496</u>
Nine Month Period Ended September 30, 2024								
	Convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated other comprehensive (loss) income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2024	—	\$ —	5,674,520	\$ 5,674	\$ 61,811,889	\$ —	\$ (54,440,789)	\$ 7,376,774
Issuance of common stock, prefunded warrants and common stock warrants, net of offering costs	—	—	2,083,262	2,083	46,396,523	—	—	46,398,606
Stock options granted in lieu of compensation	—	—	—	—	255,724	—	—	255,724
Cashless exercise of prefunded warrants	—	—	495,959	496	(496)	—	—	—
Stock-based compensation expense	—	—	—	—	1,068,011	—	—	1,068,011
Unrealized gain on marketable securities	—	—	—	—	—	123,162	—	123,162
Net loss	—	—	—	—	—	—	(9,584,781)	(9,584,781)
Balance at September 30, 2024	<u>—</u>	<u>\$ —</u>	<u>8,253,741</u>	<u>\$ 8,253</u>	<u>\$ 109,531,651</u>	<u>\$ 123,162</u>	<u>\$ (64,025,570)</u>	<u>\$ 45,637,496</u>
Three Month Period Ended September 30, 2023								
	Convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit	
	Shares	Amount	Shares	Amount				
Balance at June 30, 2023	3,331,201	\$ 24,287,211	518,140	\$ 518	\$ 19,116,831	\$ (54,228,753)	\$ (35,111,404)	
Conversion of convertible preferred stock to common stock	(3,331,201)	(24,287,211)	2,936,566	2,937	24,284,274	—	24,287,211	
Issuance of common stock upon settlement of convertible notes	—	—	795,905	796	6,988,953	—	6,989,749	
Issuance of common stock to Diffusion stockholders in reverse capitalization, net of issuance costs	—	—	1,360,244	1,360	10,337,754	—	10,339,114	
Sale of common stock	—	—	63,422	63	809,937	—	810,000	
Stock-based compensation expense, including vesting of RSUs	—	—	77	—	109,168	—	109,168	
Net income	—	—	—	—	—	2,150,362	2,150,362	
Balance at September 30, 2023	<u>—</u>	<u>\$ —</u>	<u>5,674,354</u>	<u>\$ 5,674</u>	<u>\$ 61,646,917</u>	<u>\$ (52,078,391)</u>	<u>\$ 9,574,200</u>	
Nine Month Period Ended September 30, 2023								
	Convertible preferred stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit	
	Shares	Amount	Shares	Amount				
Balance at January 1, 2023	3,331,201	\$ 24,287,211	518,140	\$ 518	\$ 18,983,339	\$ (52,268,916)	\$ (33,285,059)	
Conversion of convertible preferred stock to common stock	(3,331,201)	(24,287,211)	2,936,566	2,937	24,284,274	—	24,287,211	
Issuance of common stock upon settlement of convertible notes	—	—	795,905	796	6,988,953	—	6,989,749	
Issuance of common stock to Diffusion stockholders in reverse capitalization, net of issuance costs	—	—	1,360,244	1,360	10,337,754	—	10,339,114	
Sale of common stock	—	—	63,422	63	809,937	—	810,000	
Stock-based compensation expense, including vesting of RSUs	—	—	77	—	242,660	—	242,660	
Net income	—	—	—	—	—	190,525	190,525	
Balance at September 30, 2023	<u>—</u>	<u>\$ —</u>	<u>5,674,354</u>	<u>\$ 5,674</u>	<u>\$ 61,646,917</u>	<u>\$ (52,078,391)</u>	<u>\$ 9,574,200</u>	

See accompanying notes to unaudited condensed consolidated interim financial statements

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

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net (loss) income	\$ (9,584,781)	\$ 190,525
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Accretion of discount on marketable securities, net	(822,198)	—
Stock-based compensation expense	1,068,011	242,660
Changes in fair value of convertible debt	—	(5,424,251)
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(698,545)	(1,549,061)
Accounts payable	419,964	382,675
Accrued expenses and other liabilities	486,384	699,008
Grant receivable	651,256	—
Deferred grant revenue	—	547,051
Net cash used in operating activities	(8,479,909)	(4,911,393)
Cash flows from investing activities:		
Purchase of marketable securities	(44,467,876)	—
Maturities of marketable securities	6,500,000	—
Net cash used in investing activities	(37,967,876)	—
Cash flows from financing activities:		
Net assets assumed in connection with reverse recapitalization	—	11,887,757
Proceeds from sale of common stock, prefunded warrants and common stock warrants	46,398,606	810,000
Payment of reverse capitalization costs	—	(1,455,268)
Net cash provided by financing activities	46,398,606	11,242,489
Net (decrease) increase in cash and cash equivalents	(49,179)	6,331,096
Cash and cash equivalents at beginning of period	7,792,846	4,093,579
Cash and cash equivalents at end of period	\$ 7,743,667	\$ 10,424,675
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible notes	\$ —	\$ 6,989,749
Conversion of convertible preferred stock	\$ —	\$ 24,287,211
Merger costs in accounts payable and accrued expenses	\$ —	\$ 93,375
Stock options granted in lieu of cash bonus	\$ 255,724	\$ —
Cashless exercise of pre-funded warrants	\$ 496	\$ —

See accompanying notes to unaudited condensed consolidated interim financial statements

1. The Company and Description of Business

The Company is a corporation organized under the laws of the state of Delaware and headquartered in Boston, Massachusetts. The Company is a clinical-stage biotechnology company developing treatments for age-related neurologic disorders. The Company is currently focused on developing of its lead drug candidate, neflamapimod, an investigational, orally administered, small molecule brain penetrant that inhibits p38 α . Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in DLB and certain other major neurological disorders, and is currently being evaluated in the Company's ongoing Rewind-LB Trial, a Phase 2b study in patients with Early-Stage DLB, funded by a \$21.3 million grant from the NIA.

2. Liquidity and Capital Resources

The Company has generated negative cash flows from operations and, as of September 30, 2024, had an accumulated deficit of \$64.0 million. Based on its current operating plan, the Company believes its existing cash and cash equivalents and marketable securities on hand as of September 30, 2024, along with the remaining funds to be received from the NIA Grant, will enable the Company to fund its operating expenses and capital expenditure requirements for at least twelve months from the issuance of these unaudited condensed consolidated interim financial statements. The Company has based this estimate on assumptions that may prove to be wrong, and it could utilize its available capital resources sooner than it currently expects. The Company will continue to require additional financing to advance its current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. The Company intends to continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms, or at all. If the Company does raise additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect the Company's stockholders' rights. If the Company raises additional capital through a debt financing, it may be subject to covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on the Company's financial condition and on its ability to pursue its business plans and strategies. If the Company is unable to raise sufficient capital when needed, it may need to delay, reduce or terminate planned activities to reduce costs, including development or commercialization activities for neflamapimod. The Company might also be required to seek funds through arrangements with third parties that require it to relinquish certain of its rights to neflamapimod or otherwise agree to terms unfavorable to the Company.

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

3. Summary of Significant Accounting Policies

Basis of presentation

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

Unaudited condensed consolidated interim financial statements

The accompanying unaudited condensed consolidated interim financial statements have been prepared by the Company in accordance with US GAAP for interim information and pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in audited consolidated financial statements prepared in accordance with US GAAP have been condensed or omitted pursuant to such rules and regulations. These unaudited condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and related notes for the year ended December 31, 2023, filed as part of the Company's Annual Report.

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

Consolidation

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

Use of estimates

The preparation of unaudited condensed consolidated interim financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, grant revenue, expenses, and related disclosures. On an ongoing basis, the Company's management evaluates its estimates, including estimates related to money market accounts, clinical trial accruals, stock-based compensation expense, grant revenue, and expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ significantly from those estimates or assumptions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company maintains deposits in a financial institution in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at a financial institution that management believes to be of high credit quality, and the Company has not experienced any losses on these deposits. Management also believes that the Company is not exposed to significant credit risk as it relates to marketable securities because the Company invests in U.S. government securities and commercial paper.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value. There are *de minimis* unrealized losses on the money market funds for the period ended September 30, 2024.

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 90 days from date of purchase. These securities are carried at fair value, with unrealized gains and losses reported on the condensed consolidated statement of operations and comprehensive (loss) income and accumulated other comprehensive (loss) income within stockholders' equity until realized. Purchase discounts are accreted using the effective interest method over the term of the related security and such accretion is included in interest income on the accompanying condensed consolidated statements of operations and comprehensive (loss) income.

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The Company evaluates its investments in marketable securities for impairment at each reporting period when the fair value is below amortized cost. If the Company intends to sell the security, or it is more likely than not the Company will be required to sell the security before recovery of amortized cost, the entire impairment is included in earnings. The Company did not record any impairment on marketable securities during the three and nine months ended September 30, 2024 and 2023. There was no allowance for credit losses as of September 30, 2024 and December 31, 2023.

Fair Value of Financial Instruments

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Leases

In February 2016, the FASB issued ASU No. 2016-02, “Leases”, which establishes an ROU model that requires a lessee to recognize an ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and expense recognition in the statement of operations and comprehensive (loss) income as well as the reduction of the ROU asset. The standard provides a number of optional practical expedients in transition. The Company has elected to apply (i) the practical expedient, which allows us to not separate lease and non-lease components, for new leases and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company’s control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

The Company has elected to combine lease and non-lease components as a single component. Operating leases will be recognized on the unaudited interim condensed consolidated balance sheet as ROU assets, lease liabilities, current and lease liabilities, non-current. Fixed rent payments are included in the calculation of the lease balances, while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

Research and Development

Research and development costs are expensed as incurred and consist primarily of new product development. Research and development costs include salaries and benefits, consultants' fees, process development costs and stock-based compensation, as well as fees paid to third parties that conduct certain research and development activities on the Company's behalf.

A substantial portion of the Company's ongoing research and development activities are conducted by third-party service providers. The Company records accrued expenses for estimated preclinical study and clinical trial expenses. Estimates are based on the services performed pursuant to contracts with research institutions, contract research organizations in connection with clinical studies, investigative sites in connection with clinical studies, vendors in connection with preclinical development activities, and CMOs in connection with the production of materials for clinical trials. Further, the Company accrues expenses related to clinical trials based on the level of subject enrollment and activity according to the related agreement. The Company monitors subject enrollment levels and related activity to the extent reasonably possible and makes judgments and estimates in determining the accrued balance in each reporting period. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the unaudited condensed consolidated financial statements as prepaid or accrued research and development.

If the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from estimates. To date, the Company has not experienced significant changes in its estimates of preclinical studies and clinical trial accruals.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the unaudited interim condensed consolidated statement of operations and comprehensive (loss) income.

Stock-based Compensation

Stock-based compensation for employee and non-employee awards is measured on the grant date based on the fair value of the award and recognized on a straight-line basis over the requisite service period. The fair value of stock options to purchase common stock are measured using the Black-Scholes option pricing model. The Company accounts for forfeitures as they occur.

The fair value of stock options is determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. The Company uses the "simplified method" to estimate the expected term of stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the Company stock options, taking into consideration multiple vesting tranches. The Company utilizes this method due to lack of historical data and the plain-vanilla nature of the Company's stock-based awards.

Expected Volatility—The Company has limited information on the volatility of its common stock as the shares were not actively traded on any public markets until recently. The expected volatility is derived from the historical stock volatility of comparable peer public companies within its industry. These companies are considered to be comparable to the Company's business over a period equivalent to the expected term of the stock-based awards.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term.

Expected Dividend Rate—The expected dividend is zero as the Company has not paid, nor does it anticipate paying, any dividends on its stock options in the foreseeable future.

Grant Revenue

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

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

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the unaudited condensed consolidated interim financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to recover or settle. The effect of a change in tax rates on deferred tax assets and liabilities is recognized on the statement of operations and comprehensive loss for the period that includes the enactment date.

The deferred tax assets are recognized to the extent the Company believes that these assets are more likely than not to be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company records uncertain tax positions using a two-step process. First, the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position. Second, for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties, if any, related to unrecognized tax benefits on the interest expense line and other expense line, respectively, in the accompanying unaudited interim condensed consolidated statements of operations and comprehensive (loss) income. Accrued interest and penalties are included on the related liability lines in the unaudited interim condensed consolidated balance sheet.

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Net (Loss) Income Per Share

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted-average number of shares of common stock outstanding during each period (and potential shares of common stock that are exercisable for little or no consideration). The Pre-Funded Warrants to purchase common stock issued in connection with the 2024 Private Placement are included in the calculation of basic and diluted net (loss) income per share as the exercise price of \$0.001 per share is non-substantive and is virtually assured. Diluted (loss) income per share includes the effect, if any, from the potential exercise or conversion of securities such as common stock warrants and stock options which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that, when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For the three and nine months ended September 30, 2023, the Company was in a net income position and calculated the diluted net income per share by dividing the Company's net income by the dilutive weighted average number of share outstanding during the periods, determined using the treasury stock method and the average stock price during the period. The pre-funded warrants to purchase common stock issued in connection with the Merger are included in the calculation of basic and diluted net (loss) income per share as the exercise price of \$0.001 per share is non-substantive and is virtually assured. A reconciliation of the numerators and denominators of the basic and diluted net (loss) income per share calculations are as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Numerator				
Net (loss) income	\$ (4,753,541)	\$ 2,150,362	\$ (9,584,781)	\$ 190,525
Change in fair value of Convertible Notes	—	(4,778,251)	—	(5,424,251)
Adjusted net (loss) income	\$ (4,753,541)	\$ (2,627,889)	\$ (9,584,781)	\$ (5,233,726)
Denominator				
Weighted average shares outstanding, basic	8,702,764	3,308,302	7,861,757	1,458,415
Weighted average Convertible Notes before conversion	—	458,398	—	750,992
Weighted average shares outstanding, diluted	8,702,764	3,766,700	7,861,757	2,209,407
Net (loss) income, basic	\$ (0.55)	\$ 0.65	\$ (1.22)	\$ 0.13
Net (loss) income, diluted	\$ (0.55)	\$ (0.70)	\$ (1.22)	\$ (2.37)

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

	September 30,	
	2024	2023
Common stock warrants	2,633,868	598,457
Stock options	533,159	329,340
	<u>3,167,027</u>	<u>927,797</u>

Segments

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

Recently Issued But Not Yet Adopted Accounting Pronouncements

In January 2021, the FASB issued ASU No. 2021-01 “Reference Rate Reform (Topic 848): Scope” (“ASU 2021-01”), which was effective immediately and permits entities to elect certain optional expedients and exceptions when accounting for derivatives and certain hedging relationships affected by changes in interest rates and the transition. Additionally, ASU 2022-06 “Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848” defers the sunset date of ASC 848 from December 31, 2022 to December 31, 2024. The new guidance is effective for fiscal years beginning after December 31, 2024. The Company does not currently believe that this transition from LIBOR will have a material impact on its consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07 "Segment Reporting - Improvements to Reportable Segment Disclosures" (“ASU 2023-07”), which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. The guidance is effective for all public companies for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company expects the new guidance will have an immaterial impact on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): “Improvements to Income Tax Disclosures” (“ASU 2023-09”). ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements as well. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023-09 will have on its consolidated financial statements and disclosures.

4. Merger

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

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

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

5. Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, cash equivalents, marketable securities, accounts payable, previously outstanding convertible notes and accrued liabilities. The Company's cash, cash equivalents, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. The Company determined the fair value of its previously outstanding Convertible Notes as described in Note 9.

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

	September 30, 2024		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents (money market accounts)	\$ 6,171,726	\$ —	\$ —
Marketable securities:			
Commercial paper	\$ —	\$ 23,616,596	\$ —
U.S. treasury bonds	—	9,410,740	—
U.S. government agency bonds	—	5,885,900	—
Total assets measured at fair value	\$ 6,171,726	\$ 38,913,236	\$ —

	December 31, 2023		
Assets			
Cash equivalents (money market accounts)	\$ 7,792,846	\$ —	\$ —
Total assets measured at fair value	\$ 7,792,846	\$ —	\$ —

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.

The following is a summary of the Company's marketable securities which provides a reconciliation of amortized cost basis to fair value including cumulative unrealized gains and losses as of September 30, 2024:

	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Commercial paper	\$ 23,575,451	\$ 41,667	\$ (522)	\$ 23,616,596
U.S. treasury bonds	9,354,027	56,713	—	9,410,740
U.S. government agency bonds	5,860,596	25,304	—	5,885,900
Total	\$ 38,790,074	\$ 123,684	\$ (522)	\$ 38,913,236

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

	Nine Months Ended September 30, 2023
Balance as of January 1, 2023	\$ 12,414,000
Fair value adjustment	(646,000)
Balance as of June 30, 2023	11,768,000
Fair value adjustment	(4,778,251)
Reclassification to additional paid in capital upon conversion	(6,989,749)
Balance as of September 30, 2023	\$ —

These Convertible Notes are no longer outstanding as of September 30, 2024.

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs. The Convertible Notes are classified within Level 3 of the fair value hierarchy because the fair value measurement is based, in part, on significant inputs not observed in the market.

There were no transfers among Level 1, Level 2 or Level 3 categories in the three and nine months ended September 30, 2024 or the year ended December 31, 2023.

6. Significant Agreements and Contracts

Vertex Option and License Agreement

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

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

As part of the Vertex Agreement, the Company is obligated to make certain payments totaling up to approximately \$117.0 million upon achievement of certain regulatory and sales milestones, and royalties on net sales of products on indications covered by the Vertex Agreement. The first expected milestone events concern filing of an NDA with the FDA for marketing approval of neflamapimod (i.e., VX-745) in the U.S., or a similar filing for a non-U.S. major market, as specified in the Vertex Agreement, and such royalties will be on a sliding scale of percentages of net sales in the low- to mid-teens, depending on the amount of net sales in the applicable years. The Company is also obligated to make a milestone payment to Vertex upon net sales reaching a certain specified amount in any 12-month period. The Vertex Agreement states that royalties will be reduced by 50% during any portion of the royalty term when there is no valid claim of an issued patent within specified patent rights covering the licensed product. The Company also has the right to deduct, on a country by country basis, from royalties otherwise payable to Vertex under the terms of the Vertex Agreement, 50% of all royalties, upfront fees, milestones and other payments paid by the Company or any of the Company's affiliates or sublicensees to third parties under licenses that are necessary for the development, manufacture, sale or use of a licensed product, provided that in no event will the royalty payable to Vertex be reduced to less than 50% of the rates specified in the Vertex Agreement, subject to certain adjustments specified therein. The Company has made a total of \$100,000 in payments to Vertex related to the Vertex Agreement. No payments were made during the three and nine months ended September 30, 2024 and 2023.

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National Institute of Aging Grant

In January 2023, the Company was awarded a \$21.0 million grant from the NIA to support its RewinD-LB Trial, a Phase 2b study of neflamapimod in patients with Early-Stage DLB. In August 2024, the Company was awarded an additional \$0.3 million from the NIA. The grant monies are expected to be received over a period of three years including \$6.7 million in 2023, \$8.4 million in 2024 and \$6.2 million in 2025.

The total grant revenue recognized from the NIA Grant was \$7.6 million and \$4.7 million for the nine months ended September 30, 2024 and 2023, respectively. The total revenue recognized from the NIA Grant was \$1.9 million and \$1.5 million for the three months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, aggregate total cash funding of \$14.5 million has been received from the NIA Grant, resulting in approximately \$6.8 million in funding remaining.

The Company received access to the current year 2 (i.e., the year ending December 31, 2024) funding in the amount of \$7.3 million in February 2024. This amount was 90% of the full year 2 amount provided for in the NIA Grant due to then-current NIA policy as a result of the U.S. government being funded at such time on the basis of a continuing resolution. Consolidated appropriations acts were signed into law in March 2024, and the Company received access to the remaining 10% of the year 2 amount in June 2024.

7. Prepaid Expenses

Prepaid expenses consisted of the following:

	September 30, 2024	December 31, 2023
Clinical expenses	\$ 1,119,402	\$ 711,362
Insurance	604,543	436,859
Professional services	54,361	37,917
Dues and memberships	36,230	—
Other	74,343	70,363
Total	<u>\$ 1,888,879</u>	<u>\$ 1,256,501</u>

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2024	December 31, 2023
Employee compensation costs	\$ 739,805	\$ 1,026,054
Clinical development costs	845,063	389,045
Professional fees	449,940	309,062
State franchise and excise tax	30,456	120,456
Other	98,672	88,659
Total	<u>\$ 2,163,936</u>	<u>\$ 1,933,276</u>

9. Convertible Notes

In December 2020, EIP issued the 2020 Notes to predominantly related party investors for proceeds of \$5.1 million. In December 2021, EIP issued the 2021 Notes to predominantly related party investors for proceeds of \$6.0 million. Upon completion of the Merger in August 2023, all Convertible Notes outstanding were converted into common stock and, in certain cases, pre-funded warrants. As of September 30, 2024 and December 31, 2023, the Convertible Notes were no longer outstanding. Upon issuance, the Company elected the fair value option for the Convertible Notes in accordance with ASC 825, "Financial Instruments," pursuant to which the entire instrument, including interest expense, is measured at fair value with the initial change in fair value deemed to be a capital contribution and any subsequent changes in fair value being recorded to other income (expense) on the unaudited condensed consolidated statements of operations and comprehensive (loss) income. During the three and nine months ended September 30, 2024 there were no fair value adjustments recognized as the Convertible Notes were no longer outstanding. The fair value adjustment recognized in other income (expense) was \$4.8 million and \$5.4 million for the three and nine months ended September 30, 2023, respectively.

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

10. Commitments and Contingencies

Operating Leases

The Company has a short-term lease for office space in Boston, Massachusetts and previously had a short-term agreement to utilize membership-based co-working space in Charlottesville, Virginia, the latter of which was terminated during the three months ended March 31, 2024. Lease expense was approximately \$26,292 and \$23,000 for the nine months ended September 30, 2024 and 2023, respectively. For the three months ended September 30, 2024 and 2023, lease expense was approximately \$8,400 and \$8,000, respectively.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities and CROs to assist in the performance of research and development activities and with contract manufacturers to assist with chemistry, manufacturing, and controls related activities. Expenditures to CROs and other contract manufacturers 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 \$49,135 and a de minimus amount for the three months ended September 30, 2024 and 2023, respectively. The Company made matching contributions under the 401(k) Plan of \$136,739 and a de minimus amount for the nine months ended September 30, 2024 and 2023, 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, 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, on October 6, 2023, the court entered an order further continuing the trial date to April 24, 2024, and on March 3, 2024, based on an additional joint stipulation of the parties, the court entered an order continuing the trial date to October 23, 2024. On September 4, 2024, due to certain delays in discovery by the plaintiff, the parties filed a joint stipulation to continue the trial and certain deadlines related thereto. On October 9, 2024, based on the parties' joint stipulation, the court entered an order continuing the trial date to April 30, 2025.

The Company believes that it has meritorious defenses to the claims alleged in this matter and is defending itself vigorously. However, at this stage, the Company is unable to predict the outcome and possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company's financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company's financial position, results of operations and cash flows.

11. Stockholders' Equity and Common Stock Warrants

April 2024 Private Placement

On April 1, 2024, pursuant to and in accordance with the terms of a securities purchase agreement with certain purchasers named therein, we completed the private placement of an aggregate of 2,083,262 common shares, 2,532,285 Series A Warrants and 449,023 Pre-Funded Warrants. The aggregate upfront gross proceeds from the 2024 Private Placement were approximately \$50.0 million, before deducting approximately \$3.6 million of offering fees and expenses.

The Pre-Funded Warrants and Series A Warrants were classified as a component of stockholders' equity within additional paid-in capital. The Pre-Funded Warrants and Series A Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria.

Warrants

As of September 30, 2024, the Company had the following warrants outstanding to acquire shares of its common stock:

	Outstanding	Range of exercise price per share	Expiration dates
Historical Diffusion common stock warrants	57,965	\$26.27-\$375.14	November 2024 through February 2026
Historical EIP common stock warrants	43,618	\$19.81	April 2028
			The earlier of (i) April 1, 2027 and (ii) the date that is 180 days after the date the Exercise Conditions (as defined in the Series A Warrants) have been met
Series A common stock warrants	2,532,285	\$39.24	
Pre-funded warrants issued in April 2024 Private Placement	449,023	\$0.001	None
	<u>3,082,891</u>		

February 2024 Pre-Funded Warrant Exercise

On February 26, 2024, following the effectiveness of an amendment eliminating certain beneficial ownership limitations set forth therein, 499,995 previously outstanding pre-funded warrants to purchase common stock issued in connection with the closing of the Merger were exercised in full by the holder thereof pursuant to the cashless exercise provision of the pre-funded warrants. Upon exercise, 36 shares were withheld in lieu of a cash payment of the exercise price and the holder was issued 495,959 shares of common stock.

"At-The-Market" Sales Agreement

The Company was previously party to the 2022 Sales Agreement with BTIG. The 2022 Sales Agreement was an "at-the-market" sales agreement pursuant to which the Company was able to, from time to time and through BTIG as the Company's 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. On October 1, 2024, pursuant to and in accordance with Section 12(b) thereof, the Company notified BTIG that it was terminating the 2022 Sales Agreement effective October 11, 2024. The Company was not subject to any termination penalties or other expenses related to the termination of the 2022 Sales Agreement and, prior to termination, no shares were sold pursuant to the 2022 Sales Agreement.

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Sale of Common stock

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

12. Stock-Based Compensation Stock

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. As of September 30, 2024, there were 23,774 shares available for future issuance under the 2015 Equity Plan.

2018 Employee, Director and Consultant Equity Incentive Plan

On March 28, 2018, EIP adopted the 2018 Plan, which was assumed by the Company pursuant to and in accordance with the terms of the Merger Agreement. Under the 2018 Plan, the Company may issue incentive stock options, non-qualified stock options, stock grants, and other stock-based awards to employees, directors, and consultants, as specified in the 2018 Plan and subject to applicable SEC and Nasdaq rules and regulations. The Board has the authority to determine to whom options or stock will be granted, the number of shares, the term, and the exercise price. Options granted under the 2018 Plan have a term of up to ten years and generally vest over a four-year period with 25% of the options vesting after one-year of service and the remainder vesting monthly thereafter. As of September 30, 2024, there were no shares available for issuance.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 42,224	\$ 30,737	\$ 146,358	\$ 101,885
General and administrative	228,991	78,431	921,653	140,775
Total stock-based compensation expense	<u>\$ 271,215</u>	<u>\$ 109,168</u>	<u>\$ 1,068,011</u>	<u>\$ 242,660</u>

The following table summarizes the activity related to all stock option grants for the nine months ended September 30, 2024:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Balance at January 1, 2024	349,374	\$ 51.15		
Granted	207,284	11.23		
Cancelled/Expired	(23,499)	382.72		
Outstanding at September 30, 2024	<u>533,159</u>	<u>\$ 21.23</u>	7.5	—
Exercisable at September 30, 2024	<u>270,707</u>	<u>\$ 32.67</u>	6.5	—

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

	<u>Nine Months Ended September 30,</u> <u>2024</u>	<u>Nine Months Ended September 30,</u> <u>2023</u>
Expected term (in years)	5.25 - 5.76	5.75
Risk-free interest rate	4.06 - 4.46%	4.40%
Expected volatility	76.87 - 80.03%	81.70%
Dividend yield	—	—

At September 30, 2024, there was \$1.4 million of unrecognized compensation expense that will be recognized over a weighted-average period of 1.7 years.

During the nine months ended September 30, 2024 the Company granted 39,721 options in lieu of 2023 executive bonus compensation.

Effective May 31, 2024, the employment of the Company's former Chief Financial Officer was terminated. Based on the terms of his severance agreement, unvested shares under previously granted option awards will continue to vest on the schedule provided for in the applicable option award agreement through September 30, 2025. The Company accounted for the change in vesting terms as an improbable-to-probable modification of his stock options and recognized \$0.3 million of expense in relation to this modification during the nine months ended September 30, 2024. In addition, the exercise period for any shares under previously granted option awards vested as of May 31, 2024 was extended to September 30, 2025. The Company accounted for the change in exercise terms as a probable-to-probable modification of his stock options and recognized \$12,000 of expense in relation to this modification during the nine months ended September 30, 2024.

13. Subsequent Events

On October 1, 2024, pursuant to and in accordance with Section 12(b) thereof, the Company notified BTIG that it was terminating the 2022 Sales Agreement effective October 11, 2024. The Company was not subject to any termination penalties or other expenses related to the termination of the 2022 Sales Agreement and, prior to termination, no shares were sold pursuant to the 2022 Sales Agreement. For additional information, please refer to Note 11, Stockholders' Equity and Common Stock Warrants — "At-The-Market" Sales Agreement.

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

This discussion and analysis contains information related to historical and prospective events intended to enable you to assess our financial condition and results of operations. The information contained in this discussion and analysis should be read in conjunction with our unaudited condensed consolidated interim financial statements and the related notes contained elsewhere in this Quarterly Report, as well as the risks and uncertainties discussed under the headings, "Part II — Item 1A — Risk Factors" and "Note Regarding Forward-Looking Statements."

Introduction to CervoMed

We are a clinical-stage company developing treatments for age-related neurologic disorders. We are currently focused on developing our lead drug candidate, neflamapimod, an investigational, orally administered, small molecule brain penetrant that inhibits p38 α . Neflamapimod has the potential to treat and improve synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in DLB and certain other major neurological disorders, and is currently being evaluated in our ongoing RewinD-LB Trial, a Phase 2b study in patients with Early-Stage DLB, funded by a \$21.3 million grant from the NIA.

Overview of Our Business, Our Approach and Our Lead Drug Candidate

Our novel approach focuses on reducing the impact of inflammation in the brain, or neuroinflammation, which we believe is a key factor in the manifestation of degenerative diseases of the brain, including DLB. Chronic activation of the enzyme p38 α in the neurons (also known as nerve cells) within the brains of people with neurodegenerative diseases is believed to impair how neurons communicate through synapses (i.e., the connections between neurons). This impairment, termed synaptic dysfunction, leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in neuronal loss that leads to devastating disabilities, significant reliance on a caretaker, long term care living, and, ultimately, death. However, before neuronal loss commences, disease progression in major neurodegenerative disorders, including DLB, initially involves a protracted period of functional loss, particularly with respect to the synapses. We believe that inhibiting p38 α activity in the brain, by interfering with key pathogenic drivers of disease, has the potential to reverse the clinical progression observed in early-stage neurodegenerative diseases, and that it is possible to slow further progression by delaying permanent synaptic dysfunction and neuron death.

We believe we are a leader in the industry in developing a treatment for DLB, as we are the only company of which we are aware with an asset that has shown statistically significant improvements compared to placebo in a Phase 2a clinical trial (our AscenD-LB Trial) and that has initiated a Phase 2b clinical evaluation (our ongoing RewinD-LB Trial), from which we expect topline results in December 2024. The clinical symptoms in DLB are most directly linked to synaptic dysfunction in cholinergic neurons (i.e., neurons producing the neurotransmitter acetylcholine) in a part of the brain named the basal forebrain. Based on available preclinical and clinical data, we believe if neflamapimod is given in the early stages of certain degenerative diseases of the brain, it may reverse synaptic dysfunction and improve neuron health and function. In preclinical studies, neflamapimod has been shown to reverse the neurodegenerative process in the BFC system and correct the behavioral deficits that result from synaptic dysfunction in the BFC system. Following earlier clinical studies demonstrating blood-brain-barrier penetration, target engagement, and identification of dose-response, we obtained positive Phase 2a clinical data in patients with DLB in our AscenD-LB Trial. Specifically, statistically significant improvement was observed in patients treated with neflamapimod compared to patients treated with placebo on measures of dementia severity (as measured by CDR-SB) and functional mobility (i.e., walking ability, as measured by the TUG test) in the primary (intention-to-treat) analysis, which includes all patients randomized into the study that had at least one measurement of the endpoint analyzed. In addition, in a secondary analysis evaluating the higher of two doses in the study (40 mg TID), neflamapimod demonstrated statistically significant improvement compared to placebo in a battery of cognitive tests, particularly with respect to tests that measured attention. These preclinical results and the primary results of the AscenD-LB Trial were published in the journal Nature Communications in September 2022.

In October 2023, the major clinical neurology journal, *Neurology*, published additional analyses of the AscenD-LB Trial data that further strengthened these conclusions regarding neflamapimod's potential and identified the DLB patient population most responsive to neflamapimod treatment. In these analyses, the study results were stratified by pre-treatment levels of plasma ptau181, which recent scientific literature has identified as a blood-based biomarker to differentiate advanced DLB patients – in whom there is significant, irreversible neuronal loss in the hippocampus and associated Alzheimer's disease co-pathology – from Early-Stage DLB patients — in whom the disease is limited to synaptic dysfunction in the basal forebrain, a reversible component of the disease, and there is no associated, irreversible Alzheimer's disease-related pathology (i.e., tau pathology and neuronal loss in the region of the brain that includes the hippocampus, the medial temporal lobe). It is estimated that Early-Stage DLB patients comprise approximately 50% of the total diagnosed DLB patient population at any given time and that the remaining 50% is comprised of patients with advanced DLB, which is sometimes referred to in the scientific literature as "DLB-AD" or a form of "mixed dementia." In patients with a plasma ptau181 level of less than 2.2 pg/mL, the treatment response to neflamapimod in the AscenD-LB Trial was substantially greater than the overall patient population, with a Cohen's *d* effect size ≥ 0.7 and statistically significant vs. placebo on the CDR-SB, TUG, cognitive tests of attention and working memory. In a February 2024 publication in the *Journal of Prevention of Alzheimer's Disease*, results from our prior clinical trials of neflamapimod in Alzheimer's disease and DLB were integrated to show not only the demonstrated effects of neflamapimod on cognition and function, but on other biomarkers such as Electroencephalogram ("EEG") and basal forebrain volume and functional connectivity by Magnetic Resonance Imaging ("MRI").

Our ongoing RewinD-LB Trial is a double-blind, placebo-controlled, 16-week Phase 2b study that enrolled 159 patients with Early-Stage DLB, and is funded by a \$21.3 million grant from the NIA. The trial is intended to confirm the efficacy findings from the AscenD-LB Trial and definitively demonstrate proof-of-concept. We have utilized our subsequent analyses of the AscenD-LB Trial data and the other information described above to optimize the RewinD-LB Trial's design and bolster the trial's statistical power. Critically, the RewinD-LB Trial excluded patients with advanced DLB as evaluated by plasma ptau181 levels (i.e., the study only enrolled patients with Early-Stage DLB). To enrich for such patients during screening, the global Clinical Dementia Rating score at entry was limited to 0.5 or 1.0; based on the enrollment data in our AscenD-LB and RewinD-LB Trials, in these patients with mild or very mild dementia, we estimate that the percentage of patients with Early-Stage DLB is substantially higher (approximately 66% among patients screened in RewinD-LB) as compared to the overall DLB population as a whole (approximately 50%). Together with additional modifications to the AscenD-LB Trial design related to dosing regimen (40 mg TID) and primary endpoint (CDR-SB), sample size calculations indicate that the RewinD-LB Phase Trial has greater than 95% statistical power (approaching 100%) to meet its primary objective of demonstrating improvement relative to placebo on change in CDR-SB, a global measure of dementia severity, over the course of the study.

We completed enrollment in the RewinD-LB Trial in June 2024, completed the last patient, last visit for the 16-week placebo-controlled phase of the study in October 2024, and expect to report topline results from the placebo-controlled phase of the study in December 2024. The results of the RewinD-LB Trial are intended to provide the data necessary to finalize our design of a Phase 3 clinical trial, the general framework of which, including a 24-week treatment duration, is based on prior discussions with and feedback from the FDA. Assuming positive data in the RewinD-LB Trial, we are targeting an initiation of the Phase 3 trial in mid-2025.

In August 2024, we initiated a Phase 2a study in Strasbourg, France, to evaluate neflamapimod in up to 20 patients with mild cognitive impairment (MoCA score ≥ 18 during screening). The primary objective of the study is to obtain additional pharmacokinetic data on a dosing regimen not previously used in any of our clinical trials (80 mg BID) that may provide additional dosing flexibility for certain patient populations or indications we may target in the future. On an exploratory basis, we will also collect data on basal forebrain atrophy, as measured by MRI, and a broad range of clinical endpoints.

In addition to neflamapimod's potential to treat DLB, we believe the benefit of targeting neuroinflammation-induced synaptic dysfunction in the BFC system can be applied to other neurologic indications in which treatment of BFC dysfunction and degeneration would be expected to be clinically beneficial, including as treatment promoting recovery in the three months after ischemic stroke, as a disease-modifying treatment for early-stage Alzheimer's disease, and as a treatment for certain forms of frontotemporal dementia. In particular, we have generated preclinical evidence suggesting that neflamapimod could improve recovery after ischemic stroke in an animal model and we have received ethics committee approval to conduct a double-blind, placebo-controlled, 16-week, Phase 2a study in Australia to evaluate the effects of neflamapimod on motor recovery after ischemic stroke in approximately 90 patients, which we expect to initiate in the first quarter of 2025.

Financial Summary

As of September 30, 2024, we had cash and cash equivalents and marketable securities of approximately \$46.7 million. To date, we have not had any products approved for sale and have not generated any revenue from product sales, and our ability to do so in the future will depend on the successful development and eventual commercialization of neflamapimod (or another product candidate that we could acquire or develop in the future). We do not expect to generate revenue from product sales until such time, if ever.

Our accumulated deficit as of September 30, 2024, was \$64.0 million. We have never been profitable and we will continue to require additional capital to develop neflamapimod and fund operations for the foreseeable future. We have historically incurred net losses in each year ended since inception, except for the three and nine months ended September 30, 2023. Our net loss was \$4.8 million and \$9.6 million for the three and nine months ended September 30, 2024, respectively. Our net income was \$2.2 million and \$0.2 million for the three and nine months ended September 30, 2023, respectively. We expect our expenses will increase in connection with our ongoing activities, as we:

- advance neflamapimod through clinical trials, including a potential Phase 3 trial in DLB;
- manufacture supplies for our nonclinical studies and clinical trials;
- obtain, maintain, expand, and protect our intellectual property portfolio;
- hire additional personnel to support our operations and growth; and
- continue to operate as a public company.

Based on our current operating plan, we believe our existing cash and cash equivalents and marketable securities on hand as of September 30, 2024, along with the remaining funds to be received from the NIA Grant, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance of the unaudited condensed consolidated interim financial statements included in this Quarterly Report.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and we do not expect to do so in the near future. In January 2023, we were awarded our \$21.0 million under our NIA Grant. In August 2024, we were awarded an additional \$0.3 million under our NIA Grant. Funding from the NIA Grant is recognized as grant revenue as the qualifying expenses related thereto are incurred. For the nine months ended September 30, 2024 and 2023, \$7.6 million and \$4.7 million of grant funding was recognized, respectively. For the three months ended September 30, 2024 and 2023, \$1.9 million and \$1.5 million of grant funding was recognized, respectively.

Research and Development Expenses

Research and development expenses account for a significant portion of our operating expenses and primarily consist of costs incurred for the discovery and development of our product candidates, including:

- expenses incurred under agreements with CROs, preclinical testing organizations, consultants, and other third-party vendors, collaborators and service providers;
- costs related to production of clinical materials, including fees paid to CMOs;
- vendor expenses related to the execution of preclinical studies and clinical trials;
- personnel-related expenses, including salaries, benefits, and stock-based compensation for personnel engaged in research and development functions;
- costs related to the preparation of regulatory submissions;
- third-party license fees; and
- expenses for rent and other supplies.

We recognize research and development expenses as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators, and third-party service providers. Non-refundable advance payments made by us for future research and development activities are capitalized and expensed as the related goods are delivered and as services are performed.

Specific program expenses include expenses associated with the development of our lead product candidate, neflamapimod, including our ongoing Phase 2b RewinD-LB Trial in patients with Early-Stage DLB. Personnel and other operating expenses incurred for our research and development programs primarily relate to salaries and benefits, stock-based compensation, and facility expenses.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, neflamapimod, or for any other product candidates that we may develop or acquire. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in R&D activities related to developing neflamapimod such as conducting larger clinical trials, seeking regulatory approval and incurring expenses associated with hiring personnel to support these and other R&D efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of product candidates, including neflamapimod, is highly uncertain.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including stock-based compensation for our personnel in executive, finance and accounting, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, consulting, and tax services, insurance costs, and facility costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities and as we continue development activities. We also anticipate that we will incur increased expenses as a result of continuing to operate as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, legal, auditing, insurance expenses, investor relations activities, and other administrative and professional services.

Other Income (Expense)

Other income (expense) consists of the change in fair value of the previously outstanding Convertible Notes.

Interest Income

Interest income consists of interest earned on our marketable securities and on our cash and cash equivalent balances held with financial institutions.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations

	Three Months Ended September 30,		\$ Change	% Change
	2024	2023		
Grant revenue	\$ 1,939,751	\$ 1,526,482	\$ 413,269	27%
Operating expenses:				
Research and development	5,125,097	1,791,487	3,333,610	186%
General and administrative	2,210,927	2,410,124	(199,197)	(8)%
Total operating expenses	7,336,024	4,201,611	3,134,413	75%
Loss from operations	(5,396,273)	(2,675,129)	(2,721,144)	102%
Other income (expense):				
Other income (expense)	(3,440)	4,777,824	(4,781,264)	(100)%
Interest income	646,172	47,667	598,505	(a)
Total other income	642,732	4,825,491	(4,182,759)	(87)%
Net (loss) income	\$ (4,753,541)	\$ 2,150,362	\$ (6,903,903)	(321)%

*(a) Not meaningful

Grant Revenue

Grant revenue was \$1.9 million and \$1.5 million for the three months ended September 30, 2024 and 2023, respectively. This increase in grant revenue — all of which, for each period presented, was received pursuant to our NIA Grant, \$21.0 million of which was awarded in January 2023 and the additional \$0.3 million of which was received in August 2024, to support the RewinD-LB Trial — was related to an increase in services performed during the three months ended September 30, 2024, as a result of, among other things, a larger number of trial sites being active during the current year period. We initiated the RewinD-LB Trial in the second quarter of 2023 and completed enrollment in June 2024, with trial sites being activated on a rolling basis throughout the enrollment period.

Research and Development Expenses

Research and development expenses were \$5.1 million for the three months ended September 30, 2024, compared to \$1.8 million for the three months ended September 30, 2023. The increase of \$3.3 million was primarily due to the increase in outsourced CRO site expenses related to our RewinD-LB Trial services which ramped up progressively between initiation and the completion of enrollment as described above. In addition, the increase was due to the manufacturing of drug product batches to support further clinical development of neflamapimod, including a potential Phase 3 clinical trial in DLB, CRO expenses to support our stroke trial, non-clinical studies, and consulting services.

General and Administrative Expenses

General and administrative expenses were \$2.2 million for the three months ended September 30, 2024, compared to \$2.4 million for the three months ended September 30, 2023. The slight decrease of \$0.2 million was primarily due to fewer one-time professional fee costs that we incurred related to the Merger in the prior year. The one-time costs included D&O insurance, public relations, and accounting services.

Other Income (Expense)

There was a *de minimis* amount of other income (expense) for the three months ended September 30, 2024, compared to \$4.8 million for the three months ended September 30, 2023. The amount in the prior year period was due to adjustments to the fair value of the Convertible Notes for the three months ended September 30, 2023. The Convertible Notes converted into the right to receive common stock in connection with the closing of the Merger in August 2023 and were not outstanding during the current year period.

Interest income

Interest income was \$0.6 million for the three months ended September 30, 2024, compared to \$48,000 for the three months ended September 30, 2023. The increase was primarily due to interest earned on our increased cash equivalents and marketable securities balances in the current year period following the completion of the 2024 Private Placement in April 2024.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations

	Nine Months Ended September 30,		\$ Change	% Change
	2024	2023		
Grant revenue	\$ 7,575,972	\$ 4,654,294	\$ 2,921,678	63%
Operating expenses:				
Research and development	11,711,746	5,583,149	6,128,597	110%
General and administrative	6,850,536	4,403,590	2,446,946	56%
Total operating expenses	18,562,282	9,986,739	8,575,543	86%
Loss from operations	(10,986,310)	(5,332,445)	(5,653,865)	106%
Other income (expense):				
Other income (expense)	(3,717)	5,422,192	(5,425,909)	(100)%
Interest income	1,405,246	100,778	1,304,468	(a)
Total other income (expense)	1,401,529	5,522,970	(4,121,441)	(75)%
Net (loss) income	\$ (9,584,781)	\$ 190,525	\$ (9,775,306)	(a)

*(a) Not meaningful

Grant Revenue

Grant revenue was \$7.6 million and \$4.7 million for the nine months ended September 30, 2024 and 2023, respectively. This increase in grant revenue — all of which, for each period presented, was received pursuant to our NIA Grant, \$21.0 million of which was awarded in January 2023 and an additional \$0.3 million of which was received in August 2024, to support the RewinD-LB Trial — was related to an increase in services performed during the nine months ended September 30, 2024, as a result of, among other things, a larger number of trial sites being active during the current year period. We initiated the RewinD-LB Trial in the second quarter of 2023 and completed enrollment in June 2024, with trial sites being activated on a rolling basis throughout the enrollment period.

Research and Development Expenses

Research and development expenses were \$11.7 million for the nine months ended September 30, 2024, compared to \$5.6 million for the nine months ended September 30, 2023. The increase of \$6.1 million was primarily due to an increase in outsourced CRO site expenses related to our RewinD-LB Trial services, which ramped up progressively between initiation and the completion of enrollment as described above. In addition, the increase was driven by the manufacturing of drug product batches to support further clinical development of neflamapimod, including a potential Phase 3 clinical trial, CRO expenses to support our stroke trial, non-clinical studies, and consulting services.

General and Administrative Expenses

General and administrative expenses were \$6.9 million for the nine months ended September 30, 2024, compared to \$4.4 million for the nine months ended September 30, 2023. The increase of \$2.4 million was primarily due to public company related costs following the completion of the Merger, which closed in the third quarter of 2023. The drivers of the increase were primarily outsourced legal costs, insurance costs, headcount costs, investor/public relations costs, and stock-based compensation expense due to additional stock options granted and an amendment to our former chief financial officer's previously granted option awards in connection with his termination as an employee in May 2024 to extend the vesting and exercise periods thereunder to September 30, 2025.

Other Income (Expense)

There was a *de minimis* amount of other income (expense) for the nine months ended September 30, 2024, compared to \$5.4 million for the nine months ended September 30, 2023. The amount in the prior year period was due to adjustments to the fair value of the Convertible Notes for the nine months ended September 30, 2023. The Convertible Notes converted into the right to receive common stock in connection with the closing of the Merger in August 2023 and were not outstanding during the current year period.

Interest income

Interest income was \$1.4 million for the nine months ended September 30, 2024, as compared to \$0.1 million for the nine months ended September 30, 2023. The increase was primarily due to interest earned on our increased cash equivalents and marketable securities balances in the current year period following the completion of the 2024 Private Placement in April 2024.

Liquidity and Capital Resources

Capital Requirements

From the date of our inception through September 30, 2024, our operations have primarily been financed through the issuance of common stock, convertible preferred stock and convertible debt financings. As of September 30, 2024, we had approximately \$46.7 million of cash and cash equivalents and marketable securities. We have not generated positive cash flows from operations and as of September 30, 2024, we had an accumulated deficit of approximately \$64.0 million. In January 2023, we were awarded a \$21.0 million grant from the NIA to support the RewinD-LB Trial, which is expected to be received over a three-year period. In August 2024, we received an additional \$0.3 million from the NIA. As of September 30, 2024, total cash funding of \$14.5 million had been received from the NIA Grant.

On April 1, 2024, pursuant to and in accordance with the terms of a securities purchase agreement with certain purchasers named therein, we completed the private placement of an aggregate of 2,532,285 units, each comprised of (i) (A) one share of common stock or (B) one Pre-Funded Warrant and (ii) one Series A Warrant. The aggregate upfront gross proceeds from the 2024 Private Placement were approximately \$50.0 million, before deducting offering fees and expenses, and additional gross proceeds of up to approximately \$99.4 million may be received if the Series A Warrants are exercised in full for cash.

In addition, we were previously party to our 2022 Sales Agreement with BTIG. The 2022 Sales Agreement was an "at-the-market" sales agreement pursuant to which we were able to, 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. On October 1, 2024, pursuant to and in accordance with Section 12(b) thereof, we notified BTIG that we were terminating the 2022 Sales Agreement effective October 11, 2024. We were not subject to any termination penalties or other expenses related to the termination of the 2022 Sales Agreement and, prior to termination, no shares were sold pursuant to the 2022 Sales Agreement.

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and general and administrative expenditures. These primary uses of capital include, and we expect will continue to include, costs related to clinical research, manufacturing and development services; compensation and related expenses; costs relating to the build-out of our headquarters, other offices and laboratories; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; manufacturing costs; legal and other regulatory expenses and general overhead costs. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Any product candidates we may develop may never achieve commercialization, and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In addition, we expect to incur costs associated with operating as a public company. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements.

Based on our current operating plan, we believe our existing cash and cash equivalents and marketable securities on hand as of September 30, 2024, along with the remaining funds to be received from the NIA Grant, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance of the unaudited condensed consolidated interim financial statements included in this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through a debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we may need to delay, reduce or terminate planned activities to reduce costs, including our development or commercialization activities for neflamapimod. We might also be required to seek funds through arrangements with third parties that require us to relinquish certain of our rights to neflamapimod or otherwise agree to terms unfavorable to us.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the progress, timing, costs and results of the RewinD-LB Trial, as well as additional development plans for neflamapimod in other disease indications, such as recovery after ischemic stroke and FTD;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- our ability to reach certain milestone events set forth in our collaboration agreements and the timing of such achievements, triggering our obligation to make applicable payments;
- the hiring of additional clinical, scientific and commercial personnel to pursue our development plans, as well the increased costs of internal and external resources as to support our operations as a public reporting company;
- the cost and timing of securing manufacturing arrangements for clinical or commercial production;
- the cost of establishing, either internally or in collaboration with others, sales, marketing and distribution capabilities to commercialize neflamapimod, if approved;
- the cost of filing, prosecuting, enforcing, and defending our patent claims and other intellectual property rights, including defending against any patent infringement actions brought by third parties against us;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- our ability to establish strategic collaborations, licensing or other arrangements with other parties on favorable terms, if at all; and
- the extent to which we may in-license or acquire other product candidates or technologies.

A change in the outcome of any of these or other variables could significantly alter the costs and timing associated with the development of neflamapimod. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Cash Flows

	Nine Months Ended	
	September 30,	
	2024	2023
Net cash used in operating activities	\$ (8,479,909)	\$ (4,911,393)
Net cash used in investing activities	(37,967,876)	—
Net cash provided by financing activities	46,398,606	11,242,489
Net (decrease) increase in cash and cash equivalents	<u>(49,179)</u>	<u>6,331,096</u>

Operating Activities

For the nine months ended September 30, 2024, cash used in operating activities was \$8.5 million. The net cash outflow from operations primarily resulted from net loss of \$9.6 million and accretion of discount on marketable securities of \$0.8 million, partially offset by changes in operating assets and liabilities of \$0.9 million and by a non-cash expense of \$1.1 million for stock-based compensation.

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

Investing Activities

For the nine months ended September 30, 2024, cash used in investing activities was \$38.0 million due to the purchase of marketable securities offset by the maturities of marketable securities.

We did not have any cash provided by or used in investing activities for the nine months ended September 30, 2023.

Financing Activities

For the nine months ended September 30, 2024, cash provided by financing activities was \$46.4 million due to proceeds from the sale of common stock and the Pre-Funded Warrants for approximately \$46.4 million, partially offset by the payment of issuance costs related to the sale of common stock and the Pre-Funded Warrants, in each case, in connection with the 2024 Private Placement.

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

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, nonclinical studies and manufacturing, and other services for operating purposes. The amount and timing of contractual obligations may vary based on the timing of services. We can generally elect to discontinue the work under these agreements at any time. In the future, we could also enter into additional collaborative research, contract research, manufacturing and supplier agreements which may require upfront payments or long-term commitments of cash.

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 and Estimates

During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies and estimates from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

Recently Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in *Note 3, Summary of Significant Accounting Policies*, in the notes accompanying the unaudited condensed consolidated interim financial statements included in Part I, Item 1 of this Quarterly Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Material Weaknesses in Internal Control over Financial Reporting

In connection with the audit of the Company’s consolidated financial statements for the years ended December 31, 2023 and 2022, material weaknesses in the Company’s internal control over financial reporting were identified in relation to: (i) the recording of significant complex transactions and (ii) the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our condensed consolidated interim financial statements would not be prevented or detected on a timely basis. The identified material weaknesses, if not remediated, could result in a material misstatement to the Company’s consolidated financial statements that may not be prevented or detected. A material weakness will not be considered remediated until a remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and it has been concluded, through testing, that the newly implemented and enhanced controls are operating effectively.

On August 16, 2023, we completed the Merger. For financial reporting purposes, EIP was determined to be the accounting acquirer and, accordingly, for all periods prior to the Merger, EIP’s historical financial statements and results of operations replace and are deemed to be the Company’s financial statement and results of operations for such periods. While Diffusion was previously subject to the provisions of SOX, EIP, as a private, non-reporting operating company prior to the Merger, was not. Accordingly, upon consummation of the Merger, we began the process of integrating the pre-Merger business of EIP into Diffusion’s pre-established public company, internal control framework, including internal controls and information systems and we continue to implement measures designed to improve our internal control over financial reporting to remediate the material weaknesses. As of the date of this Quarterly Report, we continue to be actively engaged in these efforts through, among other things, adding additional review procedures by qualified personnel over complex accounting matters, and we currently expect to complete the remediation plan during the year ending December 31, 2024. However, the Company cannot predict the success of such efforts or the outcome of its assessment of the remediation efforts and the Company’s efforts may not remediate this material weakness in its internal control over financial reporting, or additional material weaknesses may be identified in the future.

Notwithstanding the material weaknesses in internal control over financial reporting described above, our management has concluded that our consolidated financial statements included in this Quarterly Report are fairly stated in all material respects in accordance with US GAAP.

Change in Internal Control Over Financial Reporting

Except as set forth above, there were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f)) that occurred during the quarter ended September 30, 2024 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

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

ITEM 1A. RISK FACTORS

As of the date of this Quarterly Report, there have been no material changes to our risk factors previously disclosed in our Annual Report.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the three months ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act), adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)	Filed herewith.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)	Filed herewith.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b)	Furnished herewith.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b)	Furnished herewith.
101.INS*	Inline XBRL Instance Document	Filed herewith.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)	Filed herewith.

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

SIGNATURES

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

CervoMed Inc.

Date: November 12, 2024

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

Date: November 12, 2024

By: /s/ William Elder
William Elder
Chief Financial Officer and General
Counsel
(Principal Financial Officer)

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, John J. Alam, MD, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CervoMed Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ John J. Alam, MD

John J. Alam, MD
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, William Elder, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CervoMed Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ William Elder

William Elder
Chief Financial Officer & General Counsel
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of CervoMed Inc. (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 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.

Date: November 12, 2024

/s/ John J. Alam, MD

John J. Alam, MD
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q of CervoMed Inc. (the “Company”) for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. Section 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.

Date: November 12, 2024

/s/ William Elder

William Elder

Chief Financial Officer & General Counsel

(Principal Financial Officer)