AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MAY 10, 2024

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

CERVOMED INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**30-0645032**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(IRS Employer Identification No.)**

20 Park Plaza, Suite 424
Boston, MA 02116
Tel: (617) 744-4400
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

John Alam, M.D.
Chief Executive Officer
20 Park Plaza, Suite 424
Boston, MA 02116
Tel: (617) 744-4400
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
William C. Hicks
Jason S. McCaffrey
Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111
Telephone: (617) 542-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS—SUBJECT TO COMPLETION, DATED MAY 10, 2024

5,064,570 Shares of Common Stock

This prospectus relates to the resale from time to time, by the selling stockholders identified in this prospectus or their donees, pledgees, assignees, transferees, distributees or other successors-in-interest (the "selling stockholders") of up to an aggregate of 5,064,570 shares of our common stock, par value $0.001 per share (the "Common Stock" or "common stock"), issued by us in a private placement on April 1, 2024 (the "2024 Private Placement"), or, with respect to the Warrant Shares (as defined below), issuable by us pursuant to the Warrants (as defined below) issued by us in the 2024 Private Placement, consisting of (i) 2,083,262 shares of our Common Stock (the "PIPE Shares"), (ii) 449,023 shares of our Common Stock issuable upon the exercise of pre-funded warrants (the "Pre-Funded Warrants") to purchase shares of our common stock held by a selling stockholder (the "Pre-Funded Warrant Shares"), and (iii) 2,532,285 shares of our Common Stock issuable upon the exercise of outstanding Series A warrants (the "Series A Warrants," and collectively with the Pre-Funded Warrants, the "Warrants") to purchase shares of our Common Stock held by the selling stockholders (the "Series A Warrant Shares," and together with the Pre-Funded Warrant Shares, the "Warrant Shares").

We are not selling any shares of Common Stock under this prospectus and will not receive any proceeds from the sale by the selling stockholders of such shares. We will, however, receive the net proceeds of any Warrants exercised for cash. We are paying the cost of registering the shares of Common Stock covered by this prospectus as well as various related expenses. The selling stockholders are responsible for any underwriting discounts and selling commissions and/or similar charges incurred in connection with the sale of the shares.

Sales of the shares by the selling stockholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both. See "Plan of Distribution" beginning on page 112 in this prospectus.

Our Common Stock is listed on the NASDAQ Capital Market under the symbol "CRVO." On May 9, 2024, the closing price of our Common Stock was $23.90.

Investing in our securities involves risks. See "Risk Factors" beginning on page 9 of this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2024

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission ("SEC"). As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC's website or its offices, as described below under the heading "Where You Can Find More Information".

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with information different from that contained in this prospectus. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby. Our business, financial condition, results of operations, and prospects may have changed since that date. We do not take any responsibility for, nor do we provide any assurance as to the reliability of, any information other than the information in this prospectus. Neither the delivery of this prospectus nor the sale of our Common Stock means that information contained in this prospectus is correct after the date of this prospectus. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

Neither we nor the selling stockholders are offering to sell or seeking offers to purchase these securities in any jurisdiction where the offer or sale is not permitted. We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities as to distribution of the prospectus outside of the United States.

INTRODUCTORY NOTES

Note Regarding Company References and Other Defined Terms

As previously disclosed in our Current Report on Form 8-K filed on August 17, 2023 with the SEC, on August 16, 2023, the Delaware corporation formerly known as "Diffusion Pharmaceuticals Inc." completed 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 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 a wholly-owned subsidiary of Diffusion (the "Merger"). Additionally, on August 16, 2023, Diffusion changed its name from "Diffusion Pharmaceuticals Inc." to "CervoMed Inc."

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

For accounting purposes, the Merger is treated as a reverse recapitalization under US GAAP and EIP 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.

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

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

Term	Definition
2015 Equity Plan	CervoMed Inc. 2015 Equity Incentive Plan, as amended
2018 Equity 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
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
AD	Alzheimer's Disease
ACA	Affordable Care Act and the Healthcare and Education Reconciliation Act
ACR20	American College of Rheumatology 20
AIA	America Invents Act
AKS	anti-kickback statute
Alpine Rewards	Alpine Rewards LLC, outside independent consultant to the Compensation Committee
ANDA	abbreviated new drug application
ASC	Accounting Standard Codification of the FASB
AscenD-LB Trial	our Phase 2a clinical trial evaluating neflamapimod for the treatment of patients with DLB, completed in the second half of 2021
Audit Committee	the Audit Committee of the Board
Bayh-Doyle Act	Bayh-Dole Act of 1980
BID	twice daily
BFC	basal forebrain cholinergic
BTIG	BTIG LLC
Board	the board of directors of the Company
Boger Trust	the Joshua S. Boger 2021 Trust DTD 12/09/2021
Bylaws	the Bylaws, as amended, of the Company
CARES Act	Coronavirus Aid, Relief, and Economic Security Act

CCPA	the California Consumer Privacy Act
CPRA	the California Privacy Rights Act
CDR-SB	Clinical Dementia Rating Sum of Boxes test
CGIC	the Alzheimer's Disease Cooperative Study-Clinician Global Impression of Change
cGMP	current good manufacturing practices
ChAT+ neurons	neurons staining positively for choline acetyl transferase
CMC	chemistry, manufacturing and controls
CMO	contract manufacturing organization
CMS	the U.S. Centers for Medicare & Medicaid Services
Compensation Committee	the Compensation Committee of the Board
Convertible Notes	collectively, the 2020 Notes and the 2021 Notes
CNS	central nervous system
Code	the U.S. Internal Revenue Code of 1986, as amended
CREATES Act	the Creating and Restoring Equal Access to Equivalent Samples Act of 2019
CRL	Complete Response Letter
CRO	contract research organization
CSF	cerebrospinal fluid
DGCL	Delaware General Corporation Law
DGM	deep grey matter
Diffusion Registration Statement	Amendment No. 2 to our Registration Statement on Form S-4, filed with the SEC on July 11, 2023, as amended from time to time
DLB	dementia with Lewy bodies
DNP	the FDA's Division of Neurology Products
DSCSA	Drug Supply Chain Security Act
EEA	European Economic Area
EEG	electroencephalogram
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
EIP Convertible Notes	collectively, the 2020 Notes and the 2021 Notes
EMA	European Medicines Agency
EOAD	Early Onset Alzheimer's Disease
EOT	end of treatment
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
FCPA	the Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FDIC	Federal Deposit Insurance Corporation
FTC	Federal Trade Commission
FTD	frontotemporal dementia
GBM	glioblastoma multiforme brain cancer
GCP	good clinical practice
GDPR	European Union General Data Protection Regulation
GLP	good laboratory practice
HIPAA	the Health Insurance Portability and Accountability of Act of 1996
HVLT	Hopkins Verbal Learning Test
IMM	irreversible morbidity and mortality
IND	investigational new drug application
IRA	Inflation Reduction Act of 2022
IRB	institutional review board
IT	information technology
MA	marketing authorization
MCI	mild cognitive impairment
MRI	magnetic resonance imaging
MSN	medial septal nucleus
Nasdaq	Nasdaq Stock Market, LLC
NbM	Nucleus basalis of Meynert
NCE	new chemical entity
NDA	new drug application

NEO	named executive officer, as defined in Rule 402(m) of Regulation S-K
NGF	nerve growth factor
NIA	the National Institute on Aging of the National Institutes of Health
NIA Grant	the $21 million grant awarded to us by the NIA in January 2023 to support the RewinD-LB Trial
NIH	National Institutes of Health
NOL	net operating loss
NTB	Neuropsychological Test Battery
NYSE	New York Stock Exchange
p38α	p38 mitogen-activated protein kinase alpha
PBM	pharmacy benefit manger
PD	Parkinson's disease
PDAB	prescription drug affordability board
PDD	Parkinson's disease dementia
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act, as amended
PET	positron emission tomography
POC	proof-of-concept
PPA	primary progressive aphasia
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
PREA	Pediatric Research Equity Act
ptau181	plasma phosphorylated tau at position 181
RA	rheumatoid arthritis
R&D	research and development
Regulation S-K	Regulation S-K promulgated under the Securities Act
REMS	Risk Evaluation and Mitigation Strategy
RewinD-LB Trial	our Phase 2b clinical trial evaluating neflamapimod for the treatment of patients with DLB, initiated in the second quarter of 2023
RLD	reference-listed drug
SAB	scientific advisory board
SAE	serious adverse events
SEC	U.S. Securities and Exchange Commission
Section 382	Section 382 of the Code
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
TCJA	Tax Cuts and Jobs Act of 2017
TID	three times daily
TSC	trans sodium crocetinate
TUG	Timed Up and Go test
UPL	upper payment limit
U.S.	United States of America
US GAAP	U.S. generally accepted accounting principles
USPTO	U.S. Patent and Trademark Office
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

Explanatory Note Regarding 2024 Private Placement

On April 1, 2024, we closed the 2024 Private Placement, pursuant to which we sold to the selling stockholders 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 PIPE 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.

The information contained in this registration statement and prospectus that is provided as of, prior to, or with respect to periods ending on or before March 31, 2024, including our consolidated financial statements for the year ended December 31, 2023, and the corresponding information regarding our liquidity, capital resources and cash runway as of December 31, 2023, set forth in, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and certain other information, does not reflect the consummation of, or our receipt of proceeds from, the 2024 Private Placement.

Note Regarding Trademarks, Trade Names, and Service Marks

This prospectus includes trademarks, trade names, and service marks owned by us or other companies. All trademarks, service marks and trade names included in this prospectus 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.

PROSPECTUS SUMMARY

This summary highlights selected information that is presented in greater detail elsewhere in this prospectus. This summary does not contain all of the information that may be important to you. You should read this entire prospectus carefully, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.

Overview

We are a clinical-stage biotechnology company focused on developing treatments for age-related neurologic disorders. We are currently focused on the development of our lead drug candidate, neflamapimod, an investigational, orally administered, small molecule brain penetrant that inhibits p38α in the neurons (nerve cells) within the brains of people with neurodegenerative diseases. Neflamapimod has the potential to treat and improve synaptic dysfunction, the reversible aspect of the underlying disease processes 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 DLB funded by a $21.0 million grant from the NIA. We expect to complete enrollment in the RewinD-LB Trial during the second quarter of 2024 and to report initial results from the placebo-controlled portion of the study during the fourth quarter of 2024.

2024 Private Placement

On March 28, 2024, we entered into the Purchase Agreement with the Purchasers for the private placement of an aggregate of 2,532,285 Units, each Unit comprised of (i) (A) one share of Common Stock or (B) one Pre-Funded Warrant, and, in each case, (ii) one Series A Warrant. A Unit comprised of one share of Common Stock and one Series A Warrant had a purchase price of $19.745 and a Unit comprised of one Pre-Funded Warrant and one Series A Warrant had a purchase price of $19.744. The 2024 Private Placement closed on April 1, 2024.

The gross proceeds for the 2024 Private Placement were approximately $50.0 million, before deducting offering fees and expenses, and up to an additional $99.4 million in gross proceeds if the Series A Warrants are fully exercised for cash. We expect to use the net proceeds from the 2024 Private Placement to fund research and development of neflamapimod, working capital and general corporate purposes. We estimate, based on our current operating plan, that the upfront, net proceeds from the 2024 Private Placement, together with our cash and cash equivalents as of December 31, 2023, and remaining funds to be receive from the NIA Grant, will be sufficient to fund our operations through the end of 2025.

Morgan Stanley and Canaccord Genuity acted as placement agents (together, the “Placement Agents”) for the 2024 Private Placement. The Placement Agents received a portion of a combined fee equal to approximately 6% of the aggregate gross proceeds from the securities sold in the 2024 Private Placement, plus the reimbursement of certain expenses.

Each Pre-Funded Warrant has an exercise price of $0.001 per Warrant Share, is immediately exercisable on the date of issuance and will not expire. Under the terms of the Pre-Funded Warrants, we may not effect the exercise of any portion of any Pre-Funded Warrant, and a holder will not have the right to exercise any portion of any Pre-Funded Warrant, which, upon giving effect to such exercise, would cause a holder (together with its affiliates) to own more than a specified beneficial ownership limitation of either 4.99% or 9.99% (as selected by such holder prior to the issuance of the Pre-Funded Warrant) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to the Company.

The Series A Warrants have an exercise price equal to $39.24 per Warrant Share, are exercisable immediately and will expire at the earlier of (i) April 1, 2027 or (ii) 180 days after the date that we make a public announcement of positive top-line data from the our Phase 2b RewinD-LB clinical trial evaluating neflamapimod for treatment of patients with dementia with Lewy bodies. Under the terms of the Series A Warrants, we may not effect the exercise of any portion of any Series A Warrant, and a holder will not have the right to exercise any portion of any Series A Warrant, which, upon giving effect to such exercise, would cause a holder (together with its affiliates) to own more than a specified beneficial ownership limitation of either 4.99% or 9.99% (as selected by such holder prior to the issuance of the Series A Warrant) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Series A Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to the Company.

Pursuant to the Purchase Agreement, we agreed to file a registration statement with the SEC within 45 days after the closing of the 2024 Private Placement (subject to certain exceptions) for purposes of registering the resale of the PIPE Shares and the Warrant Shares.

The registration statement of which this prospectus is a part relates to the offer and resale of the PIPE Shares and Warrant Shares issued to the Purchaser pursuant to the Purchase Agreement in the closing that occurred on April 1, 2024. When we refer to the selling stockholder in this prospectus, we are referring to the Purchaser named in this prospectus as the selling stockholder and, as applicable, any donee, pledgees, assignees, transferees or other successors-in-interest selling PIPE Shares or Warrant Shares received after the date of this prospectus from the selling stockholder as a gift, pledge, or other non-sale related transfer.

The securities issued in the 2024 Private Placement were issued and offered pursuant to the exemption from registration provided in Section 4(a)(2) of the Securities Act.

Risk Factors

Investing in our securities involves risks. You should carefully consider the risks described in "Risk Factors" beginning on page 9 before making a decision to invest in our securities, as well as subsequent filings with the SEC. If any of these risks actually occurs, our business, financial condition and results of operations would likely be materially adversely affected. Some of the risks related to our business and industry are summarized below.

- The Company is a clinical stage company and has incurred significant losses since its inception. The Company expects its net losses to continue for the foreseeable future. The Company is not currently profitable and may never achieve or sustain profitability. The Company is unable to predict the extent of future losses or when it might become profitable, if ever.
- The Company will require additional capital to fund its operations. If the Company fails to obtain necessary financing on acceptable terms, or at all, it may not be able to complete the development and commercialization of neflamapimod.
- The Company currently does not have, and may never have, any products that generate significant revenues.
- The Company is heavily dependent on the success of its lead product candidate, neflamapimod, which is still under clinical development. If neflamapimod does not receive regulatory approval or is not successfully commercialized, the Company's business will be materially harmed.
- The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. There is no guarantee that the Company's planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that the Company may pursue, will be successful. If the Company is ultimately unable to obtain regulatory approval for neflamapimod on a timely basis, or at all, its business will be substantially harmed.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of neflamapimod or any other product candidates the Company may develop or acquire.
- The Company has concentrated its research and development efforts on the treatment of DLB, a disease that has seen limited success in drug development. The ability to successfully develop drugs for DLB and other age-related neurologic disorders is extremely difficult and is subject to a number of unique challenges. In addition, its rationale for neflamapimod in the treatment of DLB is based on a scientific understanding of the disease that may be wrong.
- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside the Company's control.
- Results of preclinical studies and early clinical trials may not be indicative of results obtained in later trials. In addition, preliminary, topline and interim data from the Company's clinical trials that the Company may announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- If the Company does not adequately protect its proprietary rights, the Company may not be able to compete effectively.
- The Company has no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability.
- Even if neflamapimod or any other product candidate the Company develops receives marketing approval, it may fail to achieve the level of acceptance necessary for commercial success.
- The Company's future success depends in large part on the Company's ability to retain its key employees, as well as its ability to attract, train and motivate additional qualified personnel. The Company may also encounter difficulties in managing its growth, which could disrupt its operations.
- The Company has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of the Company's financial statements and have other adverse consequences. The Company may identify additional material weaknesses in its internal controls over financial reporting which it may not be able to remedy in a timely manner. If the Company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

Corporate Information

Our principal executive offices are located at 20 Park Plaza, Suite 424, Boston, Massachusetts 02116. The telephone number at our principal executive office is (617) 744-4400. Our corporate website is located at www.cervomed.com. Information contained on our website is not part of, or incorporated in, this prospectus. Our Common Stock is traded on the NASDAQ Capital Market under the symbol "CRVO."

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of any fiscal year for so long as either (1) the market value of our shares of Common Stock held by non-affiliates does not equal or exceed $250.0 million as of the prior June 30th, or (2) our annual revenues did not equal or exceed $100.0 million during such completed fiscal year and the market value of our shares of Common Stock held by non-affiliates did not equal or exceed $700.0 million as of the prior June 30th. To the extent we take advantage of any reduced disclosure obligations, it may make comparison of our financial statements with other public companies difficult or impossible.

The Offering	
Common Stock offered by the Selling Stockholders	An aggregate of 5,064,570 shares of Common Stock, including 2,083,262 PIPE Shares and 2,981,308 Warrant Shares. The selling stockholders are identified in the table commencing on page 110.
Use of proceeds	We will not receive any proceeds from the sale by the selling stockholders of the shares of Common Stock covered by this prospectus. We will, however, receive the exercise price of (i) $0.001 per share of any of the Pre-Funded Warrants, and (ii) $39.24 per share of any of the Series A Warrants, in each case, exercised for cash.
Risk factors	You should read the "*Risk Factors*" section starting on page 9 of this prospectus for a discussion of factors to consider before deciding to invest in our securities.
NASDAQ Ticker Symbol	"CRVO"

RISK FACTORS

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

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

- The Company is a clinical stage biopharmaceutical company and has incurred significant losses since its inception. The Company expects its net losses to continue for the foreseeable future. The Company is not currently profitable and may never achieve or sustain profitability. The Company is unable to predict the extent of future losses or when it might become profitable, if ever.
- The Company will require additional capital to fund its operations. If the Company fails to obtain necessary financing on acceptable terms, or at all, it may not be able to complete the development and commercialization of neflamapimod.
- The Company currently does not have, and may never have, any products that generate significant revenues.
- The Company is heavily dependent on the success of its lead product candidate, neflamapimod, which is still under clinical development. If neflamapimod does not receive regulatory approval or is not successfully commercialized, the Company's business will be materially harmed.
- The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. There is no guarantee that the Company's planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that the Company may pursue, will be successful. If the Company is ultimately unable to obtain regulatory approval for neflamapimod on a timely basis, or at all, its business will be substantially harmed.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of neflamapimod or any other product candidates the Company may develop or acquire.
- The Company has concentrated its research and development efforts on the treatment of DLB, a disease that has seen limited success in drug development. The ability to successfully develop drugs for DLB and other age-related neurologic disorders is extremely difficult and is subject to a number of unique challenges. In addition, its rationale for neflamapimod in the treatment of DLB is based on a scientific understanding of the disease that may be wrong.
- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside the Company's control.
- Results of preclinical studies and early clinical trials may not be indicative of results obtained in later trials. In addition, preliminary, topline and interim data from the Company's clinical trials that the Company may announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- If the Company does not adequately protect its proprietary rights, the Company may not be able to compete effectively.
- The Company has no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability.
- Even if neflamapimod or any other product candidate the Company develops receives marketing approval, it may fail to achieve the level of acceptance necessary for commercial success.
- The Company's future success depends in large part on the Company's ability to retain its key employees, as well as its ability to attract, train and motivate additional qualified personnel. The Company may also encounter difficulties in managing its growth, which could disrupt its operations.
- The Company has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of the Company's consolidated financial statements and have other adverse consequences. The Company may identify additional material weaknesses in its internal controls over financial reporting which it may not be able to remedy in a timely manner. If the Company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

Risks Related to the Company's Limited Operating History, Financial Condition and Need for Additional Capital

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

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, and become commercially viable. The Company has incurred net losses since its inception, and as of December 31, 2023, it had an accumulated deficit of approximately $54.4 million. The Company expects to incur net losses for the foreseeable future as it incurs significant clinical development costs related to the advancement of neflamapimod. The Company has not commercialized any products and has never generated revenue from neflamapimod or any other product. In order to obtain revenues from any product candidate, the Company must succeed, either alone or in collaboration with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. The Company may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

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

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

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

The Company expects to spend substantial amounts to complete the development of, seek regulatory approvals for, and commercialize neflamapimod, if it is ultimately approved for marketing. These expenditures will include costs related to the RewinD-LB Trial and costs associated with its license agreement with Vertex, under which the Company is obligated to make certain payments in connection with the achievement of specified events.

Until such time, if ever, that the Company can generate sufficient product revenue and achieve profitability, it expects to seek to finance future cash needs through equity or debt financings and/or corporate collaboration, licensing arrangements and grants. In connection with the Company's Annual Report, based upon the Company's then current operating plan, the Company determined that the Company's cash and cash equivalents as of December 31, 2023, would not be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements for a period of at least 12 months following the issuance of the financial statements included elsewhere in this registration statement without an additional equity or debt financing. On April 1, 2024, the Company closed the 2024 Private Placement. 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. The foregoing estimate of the Company's cash runway based on its cash and cash equivalents as of December 31, 2023 does not reflect the Company's receipt of proceeds from the 2024 Private Placement.

The Company's estimates and expectations regarding its cash runway are based on assumptions that may prove to be incorrect, and changing circumstances could cause it to consume capital faster or in different ways than the Company currently expects. For example, the RewinD-LB Trial may be more expensive, time-consuming, or difficult to implement than the Company currently anticipates. Because the length of time and activities associated with the successful development of neflamapimod are highly uncertain, the Company is unable to estimate the actual funds it will require to complete research and development and ultimately commercialize its drug candidate for one or more indications.

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

- the enrollment, progress, timing, costs and results of the RewinD-LB Trial and any future phase 3 trial evaluating neflamapimod in DLB, as well as if and when it pursues additional development plans for neflamapimod in other disease indications, such as recovery after anterior circulation ischemic stroke or EOAD;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- its ability to reach certain milestone events set forth in its collaboration agreements and the timing of such achievements, triggering obligations to make applicable payments;
- the hiring of additional clinical, scientific and commercial personnel to pursue the Company's development plans, as well the increased costs of internal and external resources as to support the Company's 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 its patent claims and other intellectual property rights, including defending against any patent infringement actions brought by third parties against the Company;
- the ability to receive additional non-dilutive funding, including the Company's pending request for additional funding under the NIA Grant and other grants from organizations and foundations;
- the Company's ability to establish strategic collaborations, licensing or other arrangements with other parties on favorable terms, if at all; and
- the extent to which the Company may in-license or acquire other product candidates or technologies.

The Company may raise additional capital in the future through a variety of sources, including public or private equity offerings, debt financings, grant funding, or strategic collaborations and licensing arrangements. However, adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company's failure to raise capital as and when needed would have a negative effect on its financial condition and its ability to pursue its business strategy. If the Company is unable to secure additional capital in sufficient amounts or on terms acceptable to the Company, it may have to delay, scale back or discontinue its development or commercialization activities for neflamapimod.

Further, to the extent that the Company raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, current stockholder's ownership interest in the Company will be diluted. In addition, any debt financing may subject the Company to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional capital through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Even if the Company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the Company or its stockholders.

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

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

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

The Company initiated its RewinD-LB Trial in the second quarter of 2023 and anticipates completing enrollment in the study in the second quarter of 2024. The Company cannot be certain that the RewinD-LB Trial or any future clinical development of neflamapimod will be successful, or that it will receive the regulatory approvals required to commercialize neflamapimod for any intended use, or that any future research and drug discovery programs undertaken by the Company will yield a drug candidate suitable for investigation through clinical trials. Even if the Company is able to successfully develop neflamapimod through approval and commercialization, any revenues from sales of the drug may not materialize for several years, if at all.

The RewinD-LB Trial is funded by a non-dilutive grant that is subject to certain conditions for funding in subsequent years.

The Company's RewinD-LB Trial is funded by a grant from the NIA, the funds from which will be disbursed over the course of the study as costs are incurred. The Company's receipt of the funds awarded to support future year costs are subject to both the availability of funds (i.e., the NIA is funded by Congress in subsequent fiscal years) and the Company's demonstration of progress in the project that is in line with the timelines provided in the grant. If such funds are no longer available, including due to a government shutdown that prohibits the disbursal of such funds, or the Company fails to demonstrate such progress, the Company's ability to continue its clinical programs may be impaired and delayed, and the Company may otherwise need to seek additional financing. For example, the Company was granted access to $7.3 million under the NIA Grant in February 2024, 90% of the full amount of the second year of funding 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 expects to receive the remaining 10% of the year 2 amount by June 30, 2024.

In addition, in December 2023, we submitted a request for supplemental funds in the amount of $4.0 million, of which, if approved, $3.9 million would be received in the current year and the remainder would be received in next the funding year. The request for supplemental funds was initially reviewed by the NIA in January 2024 but, due to the NIA working under a continuing resolution at such time, completion of the review was delayed and the request is currently scheduled to be reviewed for approval in May 2024. We currently expect to receive the remaining 10%, or $0.8 million, of the previously approved year 2 funding by June 30, 2024, the supplemental amount of $4.0 million following NIA review of our supplemental request, and the year 3 funding of $6.2 million in February 2025. However, there can be no guarantee that the NIA will approve this supplement request and that any such amounts will be received. If the Company is unable to secure additional capital through approval of the supplemental request or other means, it may have to delay, scale back or discontinue its development or commercialization activities for neflamapimod.

The Company could be subject to audit and repayment of the NIA Grant.

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

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

Pursuant to the Vertex Agreement, the Company previously acquired an exclusive license to develop and commercialize neflamapimod for the diagnosis, treatment, and prevention of AD and other CNS disorders. Under the Vertex Agreement, the Company is subject to significant potential future obligations, including payment of development milestones and royalties on net product sales, as well as other material obligations. The Vertex Agreement sets forth specific regulatory and product approval events and the related payments that the Company would be obligated to make to Vertex, if and when such events occur.

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

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

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

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

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

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

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

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

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

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

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

For example, in the Company's AscenD-LB Trial, neflamapimod demonstrated improvement versus placebo in dementia severity and motor function. Although the Company's ongoing RewinD-LB Trial was designed as a confirmatory, hypothesis-testing, randomized, double-blind placebo-controlled clinical study of neflamapimod in subjects with DLB, the RewinD-LB Trial may not be successful, or the FDA may disagree with the Company's interpretation of the clinical trial data or how those data inform the design of a potentially pivotal Phase 3 clinical trial for the Company's lead indication. In addition, even if the AscenD-LB Trial results are confirmed in the RewinD-LB Trial, the Company will still need to successfully complete additional clinical trials, including a Phase 3 trial, before it is prepared to submit an NDA for regulatory approval of neflamapimod in patients with DLB, assuming that the data collected from the Company's clinical trials are deemed sufficient to support the submission of an NDA. The Company cannot predict with any certainty if or when it might complete its development efforts and submit an NDA for regulatory approval of neflamapimod, or whether any such NDA will be approved by the FDA. An NDA or comparable foreign submission seeking marketing approval for neflamapimod also may not be accepted by FDA or foreign regulatory authorities due to, among other reasons, the content or formatting of the submission.

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

The Company is also generally required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the U.S., within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that the Company is able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB or ethics committee at each clinical site to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- inability, delay or failure in identifying, recruiting, and training suitable clinical investigators;
- delay or failure in recruiting, screening, and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- delays caused by operational issues at clinical trial sites, including insufficient staffing;
- changes to the clinical trial protocols and/or changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- clinical sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with Good Clinical Practices or other regulatory requirements, or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of the authorizing IND or foreign clinical trial application being placed on temporary or permanent clinical hold by the FDA or comparable foreign regulatory authority;
- lack of adequate funding to continue a clinical trial, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of the Company's CROs and other third parties, or the cost of clinical trials being greater than the Company anticipated;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of drug product for use in clinical trials or the inability to do any of the foregoing;
- developments on trials conducted by competitors for related technology that raise FDA or foreign regulatory authority concerns about risk to patients of a technology or in any indication more broadly;
- clinical trials of the Company's product candidates may produce negative or inconclusive results, and the Company may decide, or regulators may require the Company, to conduct additional nonclinical studies, clinical trials or abandon product development programs;

- the number of patients required for clinical trials of the Company's product candidates may be larger than the Company anticipates, enrollment in these clinical trials may be slower than it anticipates or participants may drop out of these clinical trials at a higher rate than it anticipates;
- the Company's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to the Company in a timely manner, or at all;
- regulators, the IRB or a Data Safety Monitoring Board if one is used for the Company's clinical trials, may require that the Company suspend or terminate its clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of the Company's product candidates or other materials necessary to conduct clinical trials of the Company's product candidates may be insufficient or inadequate;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO, and delays or failure by the Company's CMOs or the Company to make any necessary changes to such manufacturing process;
- the FDA or comparable foreign regulatory authorities may require the Company to submit additional data or impose other requirements before permitting it to initiate a clinical trial; or
- changes in governmental regulations or administrative actions.

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

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

- be delayed in obtaining marketing approval for its product candidates;
- not obtain marketing approval for its product candidates at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for its products or inhibit its ability to successfully commercialize the Company's products;
- be subject to additional post-marketing restrictions or requirements, including post-marketing testing; or
- have the product removed from the market after obtaining marketing approval.

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

The Company has concentrated its research and development efforts on the treatment of DLB, a disease that has seen limited success in drug development. The ability to successfully develop drugs for DLB and other age-related neurologic disorders is extremely difficult and is subject to a number of unique challenges. In addition, its rationale for neflamapimod in the treatment of DLB is based on a scientific understanding of the disease that may be wrong.

Drug development in the field of brain diseases, including age-related neurologic disorders and other neurodegenerative diseases in particular, has seen very limited success historically. There have been limited efforts by biopharmaceutical and pharmaceutical companies to develop treatments for DLB and there are no therapies available for patients that have been approved with a specific indication to treat DLB. Only symptomatic therapies that are approved for other diseases, generally either AD or Parkinson's disease, are currently utilized to manage patients with DLB. In addition, many potential disease-modifying therapies have been evaluated in other neurodegenerative diseases, particularly in AD, and these have encountered challenges in their development and, as a result, only recently two disease-modifying treatments to treat AD have been approved in the U.S. Developing a product candidate for treatment of these brain diseases is extremely difficult and subjects the Company to a number of challenges, including obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on.

The Company's approach to the treatment of DLB focuses in large part on neflamapimod's ability to inhibit the intra-cellular enzyme p38α. The expression of p38α is considered to be a critical contributor in the toxicity of inflammation, alpha-synuclein, amyloid-beta and tau to neurons and synapses, which the Company and other scientific experts believe leads to synaptic dysfunction. Synaptic dysfunction, specifically impaired synaptic plasticity, leads to disruption of episodic memory and is a significant event in the development and symptomatology of DLB.

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

Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by the Company or others may result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the Company's business and the market price of its common stock.

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

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

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

In addition, the U.S. Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase 3 of clinical development, we or our licensing partners must submit a diversity action plan to the FDA by the time a Phase 3 trial, or pivotal study, protocol is submitted to the agency for review, unless we or our licensing partners are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates or what specific information FDA will expect in such plans. However, initiation of such trials may be delayed if the FDA objects to a proposed diversity action plans for any future Phase 3 trial of our product candidates, and we or our licensing partners may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

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

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

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

In addition, from time-to-time, the Company may announce or publish preliminary, topline, or interim data from its clinical trials, which are based on a preliminary analysis of then-available data. Such results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. The Company also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, which may prove to be incomplete or flawed, and it may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data the Company previously published. As a result, preliminary and interim data are not necessarily predictive of final results and should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm the Company's business prospects.

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

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

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

The Company has in the past and may in the future conduct additional clinical trials evaluating its product candidates, including neflamapimod, outside the U.S. The acceptance of trial data from clinical trials conducted outside the U.S. by the FDA may be subject to certain conditions or may not be accepted at all, and other comparable non-U.S. regulatory authorities may have similar restrictions and conditions with respect to clinical trials conducted outside of their jurisdiction. In cases where data from non-U.S. clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not accept such foreign trial data unless: (i) the data are determined to be applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the FDA is able to validate the data through an onsite inspection, if necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many comparable non-U.S. regulatory authorities have similar approval requirements.

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

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

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

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

For example, to date, neflamapimod has been evaluated in over 200 patients, at doses up to 750 mg twice a day, and up to 24 weeks of treatment. The adverse effects (side effects) seen in more than 5% of neflamapimod-treated patients include headache (10% in neflamapimod-treated patients vs. 5% in placebo recipients), diarrhea (10% vs. 5%), abdominal pain (6% vs. 5%), respiratory infection (5% vs. 5%), and falls (5% vs. 5%). In each case, these events were generally mild and in all but one case (a case of diarrhea and abdominal pain) did not lead to treatment discontinuation. In addition, increased levels of certain "liver enzymes" in the blood are a well-known dose-dependent side effect of p38 MAPK inhibitors. These liver enzymes, aspartate aminotransferase and alanine aminotransferase, are proteins are commonly produced in the liver, the measurements of which can help doctors evaluate liver function. In an early 2000s study of neflamapimod conducted by Vertex, during 12 weeks of dosing at 250mg BID (i.e., four-fold higher daily dosing than the dose in the RewinD-LB Trial) in 44 subjects with rheumatoid arthritis, elevations in such liver enzymes levels were noted in six subjects (14%).

After the Company acquired an exclusive license from Vertex to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders, the Company submitted an IND application to the DNP in February 2015. The DNP cleared the Company's clinical trial application in March 2015. However, in August 2015, following a standard review of the long-term animal toxicity studies, the DNP placed a partial clinical hold on the Company's then ongoing Phase 2a study in AD and any subsequent studies proposed under the IND. A partial clinical hold means that the FDA suspends part of the clinical work requested under the IND (e.g., a specific protocol or part of a protocol is not allowed to proceed); however, all other protocols and/or remaining parts of the protocol are allowed to proceed under the IND. Under DNP's partial clinical hold that remains in effect for the neflamapimod IND, the agency limited administration of neflamapimod to doses that lead to plasma drug levels that provide a ten-fold safety margin to human subjects, based on the plasma drug levels in animals that had previously led to minimal or equivocal toxicity findings. The Company's current understanding of plasma drug levels achieved with neflamapimod in humans means that its investigational dosing in the U.S. is limited by this partial clinical hold to no more than 40 mg three times daily in patients weighing 50 kg (110 lbs.) or more.

The Company's ongoing RewinD-LB Trial is being conducted at 40mg three times daily (limited to patients weighing 50 kg (110 pounds) or more within the U.S., and not so limited outside the U.S.) and the Company does not expect this partial clinical hold to impact its ongoing and planned clinical trials or its current development plan for neflamapimod. With respect to the adverse effects discussed above, the patients were asymptomatic, there were no associated increases in bilirubin, and the elevations resolved with treatment discontinuation. Furthermore, no liver enzyme abnormalities were observed in the AscenD-LB Trial. However, as the Company continues the development and clinical trials of neflamapimod, treatment-related SAEs may arise in the future. Side effects that are deemed to be drug-related could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects in one of the Company's clinical trials for neflamapimod in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of the Company's product candidate in other indications. These side effects may not be appropriately recognized or managed by the treating medical staff. In addition, discovery of previously unknown class effect problems may prevent or delay clinical development and commercial approval of product candidates or result in restrictions on permissible uses after their approval. If the Company or others identify undesirable side effects caused by the mechanisms of action of a product candidate or a class of product candidates, the FDA may require the Company to conduct additional clinical trials, or to implement a REMS program prior to commercial approval. Alternatively, regulatory authorities may not approve the product candidate or, as a condition of approval, may require specific warnings and contraindications or place certain limitations on how the Company can promote the drug. Following a potential future drug product approval, regulatory authorities might also withdraw such approval due to the discovery of previously unknown safety issues relating to the product and require the Company to take its drug off the market. Any of these occurrences may harm the Company's business, financial condition and prospects significantly.

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

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

The Company may be unable to obtain regulatory approval in the U.S. or foreign jurisdictions and, as a result, be unable to commercialize its product candidates and its ability to generate revenue will be materially impaired.

The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating companies such as ours are not always applied predictably or uniformly and can change. Any analysis we perform of data from chemistry, manufacturing and controls, preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenues from the particular product candidate for which we are seeking approval.

Furthermore, obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

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

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

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

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

There are a number of programs administered by the FDA and other regulatory bodies to facilitate and expedite development of drugs in areas of unmet medical need. For example, neflamapimod received a fast track designation in October 2019 from the FDA for investigation as a treatment of DLB. Fast track designation is granted by FDA, in response to a sponsor's request, upon a determination that the product candidate is intended to treat a serious or life-threatening disease or condition and has the potential to address an unmet medical need, meaning it could provide a therapeutic option for patients where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

Fast track designation does not ensure that neflamapimod will receive marketing approval or that approval will be granted within any particular timeframe. Although fast track designation and other available FDA programs may expedite the development or approval process for certain drug candidates, such programs do not change the standards for approval, and the Company may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation for neflamapimod if it believes that the designation is no longer supported by data from the Company's clinical development program.

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

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

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

The Company and its CROs are required to comply with GLP requirements for preclinical studies and GCP requirements for clinical trials, which are regulations and guidelines enforced by the FDA and required by comparable foreign regulatory authorities. If the Company or its CROs fail to comply with GCP requirements, the clinical data generated in the Company's clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require the Company to perform additional clinical trials before approving marketing applications for the Company's product candidates. There is also no assurance these third parties will not make errors in the design, management or retention of the Company's data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could also delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the Company's clinical protocols or regulatory requirements or for any other reason, the Company's clinical trials may be extended, delayed or terminated, and it may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that it develops. As a result, the Company's financial results and the commercial prospects for neflamapimod would be harmed, its costs could increase, and its ability to generate revenue could be delayed, all of which could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

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

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

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

The Company further intends to rely on third-party CMOs for the production of commercial supply of neflamapimod if it is ultimately approved. If CMOs cannot successfully manufacture drug substance and drug product for the Company's neflamapimod program, or any other product candidate that the Company may develop or acquire in the future, in conformity to its specifications and the applicable regulatory requirements, the Company will not be able to secure or maintain regulatory approval for the use of that product candidate in clinical trials, or for commercial distribution of that product candidate, if approved. Additionally, any problems the Company experiences with any such CMOs could delay the manufacturing of its product candidates, which could harm its results of operations. All drug manufacturers and packagers are required to operate in accordance with FDA-mandated cGMPs. A failure of any of the Company's current or future CMOs to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in obtaining regulatory approval of product candidates or the ultimate launch of products based on the Company's product candidates into the market. In the event of such failure, the Company could also face fines, injunctions, civil penalties, and other sanctions. Further, if the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve a CMO's facilities for the future commercial manufacture of neflamapimod, or if it withdraws any such approval or finds deficiencies in the future, the Company may need to find alternative manufacturing facilities, which would delay its development program and significantly impact its ability to obtain regulatory approval for or commercialize neflamapimod.

In addition, if any facility of the Company's third-party drug manufacturers or suppliers were to suffer an accident or a force majeure event such as war, missile or terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of its backup generators or similar event, the Company could be materially adversely affected and any of its clinical trials could be materially delayed. An extended shut down may force the Company to procure a new research and development facility or another manufacturer or supplier, which could be time-consuming.

The Company's ongoing RewinD-LB Trial is being conducted with a drug substance (the API) previously manufactured at a third-party CMO. Future supplies of the neflamapimod drug substance could be interrupted from time to time, and the Company cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. During this period, the Company may be unable to receive investigational neflamapimod supplies or any other product candidates it may develop or acquire. In addition, a disruption in the supply of drug substance could delay the commercial launch of the Company's product candidates, if approved, or result in a shortage in supply, which would impair its ability to generate revenues from the sale of its product candidates. Growth in the costs and expenses of raw materials may also impair the Company's ability to cost effectively manufacture its product candidates.

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

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

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

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

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

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

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

Risks Related to the Company's Intellectual Property

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

The Company relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to neflamapimod. The Company's commercial success depends in part on obtaining and maintaining proprietary rights in the U.S. and in international jurisdictions, and successfully defending these rights against third-party challenges if and as they occur. The Company seeks to protect its proprietary position by filing patent applications related to neflamapimod in the U.S. and in other countries.

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

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

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

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

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

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

There is currently no composition of matter patent protection that covers neflamapimod.

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

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

Accordingly, the lack of composition of matter patent protection that covers neflamapimod may subject the Company to increased risk of third-party litigation and/or reduce third party collaborators' interest in or valuation of neflamapimod, any of which could have an adverse effect on the Company's business, financial condition or results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

The Company may be involved in lawsuits to protect or enforce its patents or other intellectual property or the intellectual property of its licensors, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe the Company's patents or other intellectual property or the intellectual property of its licensors. To cease such infringement or unauthorized use, the Company may be required to file patent infringement claims, which can be expensive and time-consuming and divert the time and attention of the Company's management and scientific personnel. The Company's pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues therefrom. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of the Company's patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the Company's patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of the Company's patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put the Company's patent applications at risk of not issuing. Defense of these claims, regardless of their merit, may involve substantial litigation expense and may be a substantial diversion of employee resources from the Company's business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, the Company's patents or patent applications. An unfavorable outcome could result in a loss of the Company's current patent rights and could require the Company to cease using the related technology or to attempt to license rights to it from the prevailing party. The Company's business could be harmed if the prevailing party does not offer it a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to the Company's interests and, even if the Company is successful, may result in substantial costs and distract the Company's management and other employees.

Even if the Company establishes infringement, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of the Company's confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of the Company's common stock.

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

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

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

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

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

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

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

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

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

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

The lives of the Company's patents may not be sufficient to effectively protect the Company's products and business.

Patents have a limited lifespan. For example, in the U.S., if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering the Company's product candidates are obtained, once the patent life has expired for a product, the Company may be open to competition from biosimilar or generic medications. The launch of a generic version of one of the Company's products, in particular, would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on the Company's business, financial condition, results of operations and prospects. As a result, the Company's patent portfolio may not provide it with sufficient rights to exclude others from commercializing product candidates similar or identical to the Company's product candidates. In addition, although upon issuance in the U.S. a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the U.S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, the Company may not receive an extension if the Company fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If the Company is unable to obtain patent term extension or restoration, or the term of any such extension is less than the Company requests, the period during which the Company will have the right to exclusively market the Company's product will be shortened and the Company's competitors may obtain approval of competing products following the Company's patent expiration and may take advantage of the Company's investment in development and clinical trials by referencing the Company's clinical and preclinical data to launch their product earlier than might otherwise be the case, and the Company's revenue could be reduced, possibly materially. If the Company does not have sufficient patent life to protect the Company's products, the Company's business and results of operations will be adversely affected.

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

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

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

The Company may rely on trade secrets or confidential know-how to protect various aspects of its business, especially where patent protection is believed by the Company to be of limited value. Due to its reliance on third parties in various aspects of its business, including CMC, R&D and collaborations, the Company must, at times, share trade secrets with such parties. The Company may also conduct joint research and development programs that require it to share trade secrets under the terms of the Company's research and development partnerships or similar agreements. Such trade secrets or confidential know-how can be difficult to protect as confidential.

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

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

Intellectual property rights do not necessarily address all potential threats to the Company's competitive advantage.

The degree of future protection afforded by the Company's intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect the Company's business or permit the Company to maintain its competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that the Company owns or has exclusively licensed;
- others may independently develop similar or alternative technologies or duplicate any of the Company's technologies without infringing the Company's intellectual property rights;
- it is possible that the Company's pending patent applications will not lead to issued patents;
- the Company may not develop additional proprietary technologies that are patentable;
- the Company may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- the Company may fail to adequately protect and police the Company's trademarks and trade secrets; and
- the patents of others may have an adverse effect on the Company's business, including if others obtain patents claiming subject matter similar to or improving that covered by the Company's patents and patent applications.

Should any of these events occur, they could significantly harm the Company's business, results of operations and prospects.

Obtaining and maintaining the Company's patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and the Company's patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, the Company's competitors might be able to enter the market, which would have a material adverse effect on the Company's business.

Risks Related to Commercialization

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

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

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

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

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

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

- the U.S. federal AKS, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- U.S. federal false claims, false statements and civil monetary penalties laws, including the U.S. federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes (i) criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services and (ii) obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- analogous state and foreign laws and regulations relating to healthcare fraud and abuse, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;
- the U.S. federal "Physician Payments Sunshine Act", which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS information related to physician payments and other transfers of value to physicians, certain advanced non-physician health care practitioners, and teaching hospitals, as well as the ownership and investment interests of physicians and their immediate family members;
- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other healthcare providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the healthcare industry;
- U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal healthcare programs; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

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

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

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

The successful commercialization of neflamapimod, or any other product candidate the Company may develop or acquire, will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Enacted and future healthcare legislation may increase the difficulty and cost for the Company to obtain marketing approval of and commercialize its product candidates, if approved, and also affect the prices it may set. Failure to obtain or maintain coverage and adequate reimbursement for the Company's product candidates, if approved, could limit its ability to market those products and decrease its ability to generate revenue.

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

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

There have recently been and may continue to be a number of significant legislative initiatives in the U.S. to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, healthcare, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the ACA, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

In August 2022, President Biden signed into law the IRA, which, among other things, requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. In addition, multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. For these and other reasons, the implementation of the IRA and its impact on the Company's business is currently unclear.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the health care and pharmaceutical supply chain, an important decision that may lead to appears to be leading to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry, and members of Congress continue to propose reforms for the PBM industry, all or each of which could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. In addition, in the last few years, several states have formed PDABs with the authority to implement UPLs on drugs sold in their respective jurisdictions. There are several pending federal lawsuits challenging the authority of states to impose UPLs, however.

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

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

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

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

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

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

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

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

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

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

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

If the FDA or a comparable foreign regulatory authority approves neflamapimod or any of the Company's future product candidates for marketing, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called "Phase 4 trials") and post-marketing surveillance to monitor the safety or efficacy of the product. If the Company or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant not-compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or the Company. If the Company or its third party providers, including the Company's CMOs, fail to comply fully with applicable regulations, then the Company may be required to initiate a recall or withdrawal of its products.

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

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

Risks Related to Ownership of the Company's Securities

The Company's stock price may be volatile, there may be limited liquidity in the trading market for the Common Stock, and the market price of its Common Stock may drop in the future.

The market price of the Company's Common Stock may be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been volatile. Some of the factors that may cause the market price of the Company's Common Stock to fluctuate include among others:

- the ability of the Company or its partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of the Company or its partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- failure of any of the Company's product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure by the Company to maintain its existing third-party license, manufacturing and supply agreements;
- failure by the Company or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to the Company's product candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by the Company's competitors;
- failure to meet or exceed financial and development projections the Company may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by the Company or its competitors;

- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the Company's ability to obtain intellectual property protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the Company, or if they issue an adverse or misleading opinions regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of its common stock by the Company or its stockholders in the future;
- the trading volume of the Common Stock;
- the limited percentage of the Company's outstanding shares that are currently freely tradeable as a result of the significant holdings of the Company's directors and officers;
- adverse publicity relating to the Company's markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in the Company's financial results.

Accordingly, the market price of the Common Stock may be highly volatile and could fluctuate widely in price as a result of these or other factors. In particular, the Company has relatively few shares of Common Stock outstanding in the "public float" as a higher percentage of the Company's outstanding shares are held by a small number of shareholders. In addition, the shares of Common Stock may be sporadically or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by shareholders may disproportionately influence the price of those shares in either direction, particularly over short periods of time. The price for such shares could, for example, decline precipitously in the event that a large number of the shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without a material reduction in share price. An active trading market for the Common Stock may never develop or be sustained. If an active market for its Common Stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

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

The Company has primarily funded its operations to date through the issuance of securities, including common stock, warrants to purchase common stock (including pre-funded warrants), convertible preferred stock, and convertible debt securities, and expects that in the future it will need to raise additional capital through similar means to fund its continued operations and liquidity needs. Assuming funding is available on acceptable terms, any future issuance of Common Stock or securities convertible for or exchangeable into Common Stock will result in dilution to the Company's existing stockholders and could depress the market price of its Common Stock. Furthermore, the terms of future financing transactions may contain provisions that restrict our operations or require us to relinquish certain rights to our product candidates or other technologies.

The Company will likely need to raise additional funds in the future to continue its operations, fund research and development, and, if approved, commercialize its product candidates. The Company currently plans to continue to finance operations with a combination of equity issuances, debt arrangements, and, potentially, licensing, or other partnering relationships. The Board may determine at any time to raise additional capital if it believes the terms are in the best interests of the Company's stockholders. In addition, the Company may also issue securities to counterparties as part of an acquisition, merger, or similar transaction, including as part of our strategic review process.

Any issuance or sale of shares, or the perception in the market of an intent to issue or sell shares in the near-term, by the Company or holders of a large number of shares could reduce the market price of the Common Stock. The Company also cannot assure you that any such sale of Common Stock or other securities will be at a price per share that is equal to or greater than the price per share paid by you for the Common Stock. Furthermore, a depressed stock price could limit the Company's ability to raise necessary capital through the sale of additional equity securities on terms that are acceptable.

In addition, in connection with the 2024 Private Placement, the Company issued the Series A Warrants pursuant to which the holders thereof are entitled to purchase an aggregate of 2,532,285 shares of Common Stock at an exercise price equal to $39.24 per share. The Series A Warrants are exercisable immediately and will expire at the earlier of (i) April 1, 2027 or (ii) 180 days after the date that the Company makes a public announcement of positive top-line data from the RewinD-LB Trial, subject to certain beneficial ownership limitations and other conditions set forth therein. Any future issuance of Common Stock upon exercise of the Series A Warrants will result in dilution to the Company's existing stockholders and could depress the market price of its Common Stock.

The Company may become obligated to pay liquidated damages if it fails to file, obtain effectiveness and maintain effectiveness of a registration statement in accordance with the terms of the securities purchase agreement related to its 2024 Private Placement.

In connection with the 2024 Private Placement, the Company granted the purchasers of securities in the offering certain resale registration rights pursuant to the terms of the Purchase Agreement. In addition to the registration rights, the purchaser may be entitled to receive liquidated damages upon the occurrence, or failure to occur, of a number of events relating to the filing, effectiveness and maintenance of effectiveness of a registration statement related to the Common Stock sold in the 2024 Private Placement. The liquidated damages will be payable upon the occurrence, or failure to occur, of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable per monthly period would be equal to 1% of the aggregate purchase price paid by the purchaser, provided, however, the maximum aggregate liquidated damages payable to the purchaser would be 5% of the aggregate amount paid by such purchaser for the purchaser of such securities in the 2024 Private Placement.

Ownership of the Common Stock is highly concentrated among its officers and directors, which may prevent the Company's stockholders from influencing significant corporate decisions and may result in perceived conflicts of interest that could cause the Company stock price to decline.

As of April 29, 2024, executive officers and directors of the Company beneficially owned, directly or indirectly, approximately 36.3% of the outstanding shares of the Common Stock. Accordingly, these stockholders, in the aggregate, may exercise substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the Company, even if such a change of control would benefit the other stockholders of the Company. The significant concentration of stock ownership may adversely affect the trading price of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

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

If existing stockholders of the Company sell, or indicate an intention to sell, substantial amounts of Common Stock in the public market after certain legal and contractual restrictions on resale lapse, the trading price of the Common Stock could decline.

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

The trading market for the Common Stock will be influenced by the research and reports that equity research analysts may publish about it and its business from time to time. Equity research analysts may elect not to provide or continue research coverage of the Common Stock, which may adversely affect the market price of the stock. In the event the Company does have equity research analyst coverage at any given time, the Company will not have any control over the analysts, or the content and opinions included in their reports. The price of the Common Stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of the Company or fails to publish reports on the Company regularly, demand for the Common Stock could decrease, which in turn could cause its stock price or trading volume to decline.

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

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

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

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

- allow the authorized number of the Company's directors to be changed only by resolution of the Board;
- limit the manner in which stockholders can remove directors from the Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to the Board;
- limit who may call stockholder meetings and the Company stockholders' ability to act by written consent;
- authorize the Board to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the Board; and
- require the approval of the holders of at least 2/3 of the votes that all the Company's stockholders would be entitled to cast to amend or repeal specified provisions of the Company's certificate of incorporation, as amended, or for stockholders to amend or repeal the Company's amended and restated bylaws.

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

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

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

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

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

The Company's current expectation is that it will retain future earnings, if any, to fund the development and growth of the Company's business. As a result, capital appreciation, if any, will be your sole source of potential gain on an investment in the Company's Common Stock for the foreseeable future.

General Risks Related to the Company's Business and Operations

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

The Company has a small number of employees, and it is highly dependent on the principal members of its management team, including its President and Chief Executive Officer, John Alam, M.D. Although the Company has employment agreements or offer letters with its executive officers and certain key employees, these agreements do not prevent them from terminating their services at any time.

Competition in the biotechnology industry for skilled and experienced employees is intense, particularly in the greater Boston, Massachusetts area, where the Company's headquarters is located, and the Philadelphia, Pennsylvania area, where approximately 50% of the employee's workforce is located. The Company also faces competition for the hiring of scientific and clinical personnel from universities and research institutions, many of which are near the Company's headquarters. The loss of the services of any member of the Company's senior management, clinical development or scientific staff, or any other key employee, may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on the Company's business, operating results and financial condition.

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

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

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

The Company has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of the Company's financial statements and have other adverse consequences. The Company may identify additional material weaknesses in its internal controls over financial reporting which it may not be able to remedy in a timely manner. If the Company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

The Company is subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that the Company maintain effective disclosure controls and procedures and internal control over financial reporting. The Company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that the Company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. The Company may experience difficulty in meeting these reporting requirements in a timely manner.

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 the Company's consolidated financial statements would not be prevented or detected on a timely basis. The identified material weaknesses, if not corrected, could result in a material misstatement to the Company's consolidated financial statements that may not be prevented or detected. The Company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its consolidated financial statements.

For example, 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 related to (i) the Company's recording of significant complex transactions, and (ii) the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts. The Company may identify additional material weaknesses in its internal controls over financing reporting in the future which it may not be able to remedy in a timely manner. Any material weaknesses will not be considered remediated until a remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and it has been concluded, through testing, that the newly implemented and enhanced controls are operating effectively.

If the Company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, the Company may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. More generally, any failure by the Company to implement and maintain effective internal control over financial reporting could result in errors in the Company's financial statements that could result in a restatement of the Company's financial statements and could cause the Company to fail to meet its reporting obligations, any of which could diminish investor confidence in the Company and cause a decline in the price of the Company's common stock.

The Company's disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

The Company is subject to the periodic reporting requirements of the Exchange Act and its disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by the Company in reports it files or submits under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. The Company believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

For example, 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 and, as a result, our principal executive officer and former principal financial officer concluded that our disclosure controls and procedures were ineffective as of December 31, 2023.

The Company's information technology systems, or those of its vendors, collaborators or other contractors or consultants, may fail or suffer security incidents, loss of data and other disruptions, which could result in a material disruption of its product development programs, compromise sensitive information related to its business or prevent it from accessing critical information, potentially exposing it to liability or otherwise adversely affecting its business.

In the ordinary course of the Company's business, the Company collects and stores sensitive data, intellectual property, and proprietary business information. This data encompasses a wide variety of business-critical information including research and development information, clinical trial information, commercial information, and business and financial information. The Company faces risks relative to protecting this critical information including loss of access, unauthorized disclosure, unauthorized modification, and inadequate monitoring of its controls over these risks.

Despite the implementation of security measures, the Company's internal IT systems and those of its current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to system failures, accidents, security incidents, damage, interruption or data theft from computer viruses, computer hackers, malicious code, employee theft or misuse, ransomware, social engineering (including phishing attacks), denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of the Company's IT systems and networks and the confidentiality, availability and integrity of the Company's data. There can be no assurance that the Company will be successful in preventing cybersecurity incidents or successfully mitigating their effects.

Any such disruption or security incident could cause interruptions to its operations and result in disruption of the Company's development programs and business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in the Company's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. If the Company were to experience a significant cybersecurity incident that impacts its information systems or data, the costs associated with the investigation, remediation, and potential notification of the cybersecurity incident to counterparties, regulatory authorities, and data subjects could be material. In addition, the Company's remediation efforts may not be successful. Cybersecurity incidents could also lead to significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. In addition, the Company's recently-increased remote workforce could increase the Company's cybersecurity risk, create data accessibility concerns, and make the Company more susceptible to communication disruption.

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

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

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

For example, in August 2014, Paul Feller, the former Chief Executive Officer of the Company's legal predecessor, filed a complaint asserting various causes of action related to his past affiliations with the Company's legal predecessor. While the Company believes it has meritorious defense to the claims alleged in this matter and is defending itself vigorously, the Company is unable to predict the outcome and possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company's financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company's consolidated financial position, results of operations and cash flows.

Now that the Merger has closed, there can be no further recourse by either party or its stockholders for a breach of representation or warranty by any of the parties to the Merger Agreement.

The representations and warranties of Diffusion, EIP and Merger Sub contained in the Merger Agreement or any certificate or instrument delivered pursuant to the Merger Agreement terminated at the Effective Time. To the extent that any such party's breach of any representations and warranties is discovered or occurs in the future, there is no mechanism pursuant to which the other parties can pursue recourse or remedy.

The Company's business is, or may in the future become, subject to complex and evolving U.S. and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and the Company's actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm its business.

A wide variety of provincial, state, national, and international laws and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy-related laws and regulations are evolving and may result in increased regulatory and public scrutiny and escalating levels of enforcement and sanctions. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. For example, California has enacted the CCPA, which went into effect in January of 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase the Company's compliance costs and potential liability with respect to other personal information the Company collects and processes about California residents. Additionally in 2020, California voters passed the CPRA, which went into full effect on January 1, 2023. The CPRA significantly amends the CCPA, potentially resulting in further uncertainty, additional costs related to our compliance efforts and additional potential for harm and liability if we fail to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority. In addition to California, more U.S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas will take effect in 2024. In addition, laws in other U.S. states are set to take effect beyond 2024, and additional U.S. states have proposals under consideration, all of which could increase the Company's regulatory compliance costs and risks, exposure to regulatory enforcement action and other liabilities.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy framework called the GDPR which became fully effective in May 2018 and governs the collection and use of personal data in the European Union, including by companies outside of the European Union. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. The GDPR imposes stringent data protection requirements and provides for penalties for noncompliance of up to the greater of €20 million or four percent of worldwide annual revenues. The GDPR and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. The Company may be required to devote significant additional resources to complying with these laws and regulations, and it is possible that the GDPR or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with the Company's current policies and practices.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, the Company may find that it is violating the laws or regulations of another jurisdiction. Despite the Company's efforts, the Company may not have fully complied in the past and may not in the future. That could require the Company to incur significant expenses, which could significantly affect its business. Failure to comply with data protection laws or to protect personal data or other data the Company processes or maintains may expose the Company to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, potential significant fines, penalties and other liabilities if it is found to be non-compliant, and damage to the Company's reputation, any of which could materially affect its business, financial condition, results of operations and prospects. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm the Company's business and reputation.

Past or future transactions resulting in an ownership change under Section 382 of the Code may subject the Company's NOL carryforwards and certain other tax attributes to limitation.

As of December 31, 2023, the Company had U.S. federal NOL carryforwards of approximately $38.9 million. Under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change" (within the meaning of Section 382), the corporation's NOL carryforwards and certain other tax attributes (such as research tax credits) arising before the ownership change are subject to limitation on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points (by value) over a rolling three-year period. Similar rules may apply under state tax laws. Past or future transactions to which the Company is a party may, alone or in the aggregate, result in such an ownership change and, accordingly, the Company's NOL carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use in the future. Consequently, even if the Company achieves profitability, it may not be able to utilize a material portion of its NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, the Company's existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

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

The Company incurs significant legal, accounting and other expenses associated with public company reporting requirements. The Company also incurs costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC, as well as the rules and regulations of Nasdaq. These laws, rules and regulations also may make it difficult and expensive for the Company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the Company to attract and retain qualified individuals to serve on the Company's Board or as executive officers of the Company, which may adversely affect investor confidence in the Company and could cause the Company's business or stock price to suffer.

The Company may fail to comply with evolving privacy and data protection laws, which could adversely affect the Company's business, results of operations and financial condition.

In California, the CCPA, which became effective in 2020, broadly defines personal information, gives California residents expanded individual privacy rights and protections and provides for civil penalties for violations and a private right of action for data breaches. Further, the CPRA, which became effective in 2023 and amends the CCPA, creates additional obligations with respect to processing and storing personal information. While there is limited exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may regulate or impact our processing of personal information depending on the context. Unlike other state privacy laws, the CCPA also regulates personal information collected in a business to business and in human resources contexts. Further, there continues to be some uncertainly about how provisions of the CCPA and the new regulations will be interpreted and how the law will be enforced. In addition to the CCPA, broad consumer privacy laws recently went into effect in Virginia on January 1, 2023, in Colorado and Connecticut on July 1, 2023, and in Utah on December 31, 2023. New privacy laws will also become effective in Florida, Montana and Texas in 2024, in Tennessee and Iowa in 2025, and in Indiana in 2026 and numerous other states are considering new privacy laws. Furthermore, other U.S. states, such as New York, Massachusetts, and Utah have enacted stringent data security laws and numerous other states have proposed similar privacy laws. The existence of differing comprehensive privacy laws in different states in the country will make the Company's compliance obligations more complex and costly and may require us to modify the Company's data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

In the European Union and the United Kingdom, the Company may also face particular privacy, data security, and data protection risks in connection with requirements of the GDPR. The GDPR applies to any company established in the European Union as well as to those outside the European Union if they collect and use personal data in connection with the offering of goods or services to individuals in the European Union or the monitoring of their behavior. The GDPR imposes a broad range of data protection obligations on companies subject to the GDPR, including, for example, imposing obligations on companies around how they process personal data, stricter requirements relating to processing health and other sensitive data, ensuring there is a legal basis to justify the processing of personal data, stricter requirements relating to obtaining consent of individuals, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, implementing safeguards to protect the security and confidentiality of personal data, taking certain measures on engagement with third parties, restrictions on transfers outside of the European Union to third countries deemed to lack adequate privacy protections, and has created onerous new obligations and liabilities on services providers or data processors. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. Moreover, data subjects can claim damages resulting from infringement of the GDPR. The GDPR further grants non-profit organizations the right to bring claims on behalf of data subjects. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase the Company's cost of providing the Company's products and services or even prevent us from offering certain services in jurisdictions that the Company may operate in. The GDPR may increase the Company's responsibility and liability in relation to personal data that the Company processes where such processing is subject to the GDPR, and the Company may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Ensuring the Company's continued compliance with the GDPR is a rigorous and time-intensive process that may increase the Company's cost of doing business or require us to change the Company's business practices, and despite those efforts, there is a risk that the Company may be subject to fines and penalties, litigation, and reputational harm in connection with the Company's European activities. Many jurisdictions outside of U.S. and Europe are also considering and/or enacting comprehensive data protection legislation that could have an impact on market expansion and clinical trials as well.

On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the European Union to the United States – the European Union-U.S. Data Privacy Framework, which provides European Union individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the perceived deficiencies in the protection of European Union-U.S. data transfers raised in the *Maximilian Schrems vs. Facebook* (Case C-311/18) decision by the Court of Justice of the European Union. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Because the interpretation and application of many privacy and data protection laws (including those state laws in the U.S. and the GDPR), commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with the Company's existing data management practices and policies. If so, in addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, the Company could be required to fundamentally change the Company's business activities and practices or modify the Company's solutions, which could have an adverse effect on the Company's business. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and security or data security laws, regulations, and policies, could result in additional cost and liability to us, damage the Company's reputation, inhibit the Company's ability to conduct trials, and adversely affect the Company's business.

The Company's business and operations could suffer in the event of system failures, cyberattacks, or deficiency in the Company's cyber security.

The Company relies on information technology systems and networks, including third-party "cloud-based" service providers, and the Company's third-party CROs, to process, transmit and store electronic information in connection with the Company's business activities. This includes crucial systems such as email, other communication tools, electronic document repositories, and archives. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of the Company's systems and networks and the confidentiality, availability and integrity of the Company's data. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, the Company may be unable to anticipate these techniques or implement adequate preventative measures. The Company may also experience security breaches that may remain undetected for an extended period. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. As of the date of this registration statement, there have been no cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company's business strategy, results of operations, or financial condition. However, there can be no assurance that the Company will be successful in preventing cyber-attacks or successfully mitigating their effects.

The Company's business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws.

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

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for clinical trial applications and/or marketing applications for new drugs to be reviewed or approved, which would adversely affect the Company's business. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical staff and stop critical activities. If a prolonged government or slowdown shutdown occurs, it could significantly impact the ability of the NIA to disburse funds for the Company's clinical trial and for the FDA to timely review and process the Company's regulatory submissions, which could have a material adverse effect on the Company's business.

For example, the Company received access to $7.3 million under the NIA Grant in February 2024, 90% of the full amount of current year funding provided for in the NIA Grant, due to current NIA policy as a result of the U.S. government currently being funded on the basis of a continuing resolution. The timing of the Company's receipt of the remaining 10%, or $0.8 million, of current year funding is dependent upon and subject to U.S. congressional approval of a final appropriations bill.

Future government shutdowns or slowdowns could also result in delays in the Company's interactions with the SEC and other government agencies, which could impact the Company's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

U.S. federal income tax reform or other changes in applicable tax law could adversely affect the Company's business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department and other governmental bodies. In recent years, many such changes have been made and may continue to occur in the future. For example, in March 2020, the CARES Act was signed into law, which included certain changes in tax law intended to stimulate the U.S. economy in response to the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Additionally, in December 2017, the TCJA was signed into law, which significantly reformed the Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in the Company's common stock. For example, under the TCJA, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year's taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. The CARES Act modified the TCJA with respect to the TCJA's limitation on the deduction of NOLs and provided that NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminated the limitation on the deduction of NOLs to 80 percent of current year taxable income for taxable years beginning before January 1, 2021 (but reinstated the limitation for taxable years beginning after December 31, 2020). As a result of such limitations, the Company may be required to pay federal income tax in some future year notwithstanding that it had a net loss for all years in the aggregate.

More generally, recent and future changes in tax laws could have a material adverse effect on the Company's business, cash flow, financial condition or results of operations.

The Company faces risks associated with increased geopolitical uncertainty.

Ongoing and potential military actions across the globe, including the ongoing conflicts in Ukraine and the Middle East, as well as the sanctions, bans and other measures taken by governments, organizations and companies against the involved countries and certain citizens of those countries in response thereto, has increased the global political uncertainty and has strained the relations between a significant number of governments, including the U.S. The duration and outcome of these conflicts, any retaliatory actions or escalation, and the impact on regional or global economies is unknown but could have a material adverse effect on the Company's business, financial condition and results of its operations.

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

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

Epidemics, pandemics or other public health crises, including COVID-19, could adversely affect the Company's business.

The Company's operations could be significantly adversely affected by the effects of a widespread outbreak of epidemics, pandemics or other health crises, including COVID-19. The Company cannot accurately predict the impact of epidemics and pandemics would have on our operations and the ability of third parties to meet their obligations under contracts or arrangements with the Company, including uncertainties relating to the ultimate geographic spread of epidemics and pandemics, the severity of the underlying diseases, the duration of outbreaks, and the length of travel and quarantine restrictions imposed by governments of affected countries. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could further affect the Company's operations and ability to finance the Company's operations.

Political uncertainty may have an adverse impact on the Company's operating performance and results of operations.

General political uncertainty may have an adverse impact on the Company's operating performance and results of operations. In particular, the United States continues to experience significant political events that cast uncertainty on global financial and economic markets, especially in light of the upcoming presidential election. It is presently unclear exactly what actions a new administration in the United States would implement, and if implemented, how these actions may impact the pharmaceutical industry in the United States.

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

The Company holds its cash and cash equivalents that it uses to meet working capital needs in deposit accounts at certain third party financial institutions. The balances held in these accounts may exceed the FDIC, standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which the Company holds such funds fails or is subject to significant adverse conditions in the financial or credit markets, the Company could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact the Company's short-term liquidity and ability to meet its obligations.

For example, on March 10, 2023, Silicon Valley Bank, and on March 12, 2023, Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of Silicon Valley Bank and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the U.S. Department of the Treasury, the Federal Reserve and the FDIC. While the Company did not hold any of its funds in accounts with either of these institutions, if financial institutions in which the Company holds funds for working capital were to fail, the Company cannot provide any assurances that such governmental agencies would take action to protect its uninsured deposits in a similar manner.

The Company may also, from time to time, maintain investment accounts with other financial institutions in which it holds its investments and, if access to the funds the Company uses for working capital is impaired, the Company may not be able to sell investments or transfer funds from its investment accounts to new accounts on a timely basis sufficient, or without incurring a loss or penalty as a result of such sale, to meet its working capital needs.

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

One or more of the Company's stockholders may from time to time seek to acquire a significant or controlling stake in the Company, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes to the Company's Board or corporate governance policies. Campaigns by stockholders to effect changes at publicly traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, could disrupt the Company's operations and divert the attention of the Company Board and senior management, and could adversely affect the Company's operations, financial condition, and the value of its common stock.

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

As previously announced, in connection with Diffusion's strategic review process during 2022-23, Diffusion made the decision to voluntarily pause the development program for TSC, Diffusion's lead drug candidate prior to the Merger. Currently, the Company does not intend to pursue the development of TSC and believes the primary path available to derive value from its TSC-related assets would be to find a suitable acquiror or licensee. Although the Company's management has contacted numerous parties to assess their potential interest in such a transaction, to date, the Company has been unable to identify an interested counterparty. Furthermore, even if the Company is able to identify such a counterparty, supporting diligence activities conducted by potential acquirors or licensees and negotiating the financial and other terms of an agreement or license are typically long and complex processes, and the results of such processes cannot be predicted. There can be no assurance that the Company will enter into any transaction as a result of these effort or that any transaction involving the Company's TSC-related assets will be entered into or, if entered into, will be on terms that are favorable to the Company. Furthermore, the Company cannot predict the impact that such a transaction or, alternatively, a failure to monetize the TSC assets in any material way, might have on its stock price.

Artificial intelligence presents risks and challenges that can impact the Company's business including by posing security risks to confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to the Company's business operations. The Company may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. The Company's vendors may incorporate generative artificial intelligence tools into their offerings, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit the Company's or its vendors' ability to maintain an adequate level of service and experience. If the Company, its vendors, or its third-party partners experience an actual or perceived violation of applicable privacy or data protection laws or regulations, or a cybersecurity incident due to the use of generative artificial intelligence, the Company could be subject to regulatory fines, investigations, enforcement actions, penalties and other liabilities, claims for damages from affected individuals, and the Company may lose valuable intellectual property and confidential information and its reputation and the public perception of the effectiveness of its privacy or cybersecurity measures could be harmed. Any of these outcomes could damage the Company's reputation, result in the loss of valuable property and information, and adversely impact its business.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus, 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 prospectus. In addition, even if our results of operations, financial condition, liquidity, and prospects are consistent with the forward-looking statements contained in this prospectus, 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 registration statement. We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements also include statements regarding our intentions, beliefs, projections, outlook, analyses or expectations concerning, among other things:

- our cash balances and our ability to obtain additional financing in the future and continue as a going concern;
- the success and timing of our ongoing 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;
- our ability to successfully integrate the historical businesses of EIP and Diffusion and realize the anticipated benefits of the Merger;
- recently enacted and future legislation related to the healthcare system;
- other regulatory developments in the U.S., European Union, and other foreign jurisdictions;
- our ability to satisfy the continued listing requirements of the Nasdaq or any other exchange on which our securities may trade in the future;
- uncertainties related to general economic, political, business, industry, and market conditions, including the continued availability of funding for the NIA to support disbursements under our previously received grant and
- other risks and uncertainties, including those discussed under the heading "Risk Factors" herein and in our other public filings.

As a result of these and other factors, known and unknown, actual results could differ materially from our intentions, beliefs, projections, outlook, analyses, or expectations expressed in any forward-looking statements in this prospectus. Accordingly, we cannot assure you that the forward-looking statements contained in this prospectus 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 prospectus 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 prospectus 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.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale or other disposition of shares of our Common Stock beneficially owned by the selling stockholders pursuant to this prospectus. Upon any exercise of the Warrants for cash, the applicable selling stockholder would pay us the exercise price set forth in the applicable Warrant.

Each Pre-Funded Warrant has an exercise price equal to $0.001 per share, and if all 449,023 Pre-Funded Warrants are exercised on a cash basis, we will receive proceeds of approximately $449. Each Series A Warrant has an exercise price equal to $39.24 per share, and if all 2,532,285 Series A Warrants are exercised on a cash basis, we will receive proceeds of approximately $99.4 million. We expect to use any such proceeds primarily to fund research and development of our clinical-stage product candidate, neflamapimod, working capital and general corporate purposes.

The Pre-Funded Warrants are exercisable on a net exercise cashless basis. The Series A Warrants are only exercisable on a net exercise cashless basis if, after six months from the date of their initial issuance, there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the shares issuable upon exercise of such warrants. If any of the Warrants are exercised on a cashless basis, we would not receive any cash payment from the applicable selling stockholder upon any such exercise.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of shares of our Common Stock to be sold by the selling stockholders pursuant to this prospectus. Other than registration expenses, the selling stockholders will bear their own broker or similar commissions payable with respect to sales of shares of our Common Stock.

MARKET INFORMATION AND DIVIDEND POLICY

Market Information

Our Common Stock is quoted on the NASDAQ Capital Market under the symbol “CRVO”. On May 9, 2024, the last reported sale price for our Common Stock was $23.90 per share.

Dividend Policy

We have never declared or paid cash dividends on our Common Stock, and currently do not plan to declare dividends on shares of our Common Stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

MANAGEMENT'S DISCUSSION AND ANALYSIS AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our audited consolidated financial statements and the accompanying notes thereto included elsewhere in this registration statement. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for the business and related financing, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 12E of the Exchange Act that involve risks and uncertainties. As a result of many factors, including those factors set out under the section entitled "Risk Factors" included in this registration statement, actual results could differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a clinical-stage biotechnology company focused on developing treatments for age-related neurologic disorders. We are currently focused on the development of our lead drug candidate, neflamapimod, an investigational, orally administered, small molecule brain penetrant that inhibits p38α in the neurons (nerve cells) within the brains of people with neurodegenerative diseases. Neflamapimod has the potential to treat and improve synaptic dysfunction, the reversible aspect of the underlying disease processes 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 DLB funded by a $21.0 million grant from the NIA. We expect to complete enrollment in the RewinD-LB Trial during the second quarter of 2024 and to report initial results from the placebo-controlled portion of the study during the fourth quarter of 2024.

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 p38α in the neurons (nerve cells) within the brains of people with neurodegenerative diseases is believed to impair how neurons communicate through synapses (the connections between neurons). This impairment, termed synaptic dysfunction, leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in neuronal loss that leads to devastating disabilities, 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 p38α 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 has initiated a Phase 2b clinical evaluation (our ongoing RewinD-LB Trial), from which we expect initial results before the end of 2024. The clinical symptoms in DLB are most directly linked to synaptic dysfunction in cholinergic neurons (neurons producing the neurotransmitter acetylcholine) in a part of the brain named the basal forebrain. 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. Following earlier clinical studies demonstrating blood-brain-barrier penetration, target (p38α) 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 that includes all patients randomized into the study that had at least one measurement of the endpoint analyzed. In addition, in a secondary analysis, neflamapimod demonstrated statistically significant improvement compared to placebo in a battery of cognitive tests, particularly with respect to tests that measured attention.

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 efficacy and identified the DLB patient population most responsive to neflamapimod treatment. In these analyses, the results were stratified by pre-treatment levels of plasma ptau181, which recent scientific literature has identified as a biomarker to differentiate DLB patients with AD-associated co-pathology – a form of mixed dementia which we sometimes refer to as "DLB+AD" – from DLB patients without AD-associated co-pathology – which we sometimes refer to as "pure DLB." In pure DLB patients, who generally represent early-stage patients with limited neurodegeneration in the hippocampus, the treatment response to neflamapimod in the AscenD-LB Trial was substantial (Cohen's *d* effect size ≥ 0.7 and statistically significant vs. placebo on the CDR-SB, TUG, cognitive tests of attention and working memory) and greater than the overall patient population. In a February 2024 publication in the Journal of Prevention of Alzheimer's Disease, results from our prior clinical trials of neflamapimod in AD and DLB were integrated to show not only the demonstrated effects of neflamapimod on cognition and function, but on other biomarkers such as EEG and brain volume and functional connectivity in the basal forebrain.

Our ongoing RewinD-LB Trial is a double-blind, placebo-controlled, 16-week Phase 2b study in 160 patients with pure DLB funded by a $21.0 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 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 will exclude patients with Alzheimer's disease related co-pathology as evaluated by plasma ptau181 levels (i.e., the study will only enroll patients with pure DLB) and, to enrich for such patients, the global CDR-SB score at entry will be limited to 0.5 or 1.0. Together with additional modifications to the Phase 2a design related to dosing regimen and primary endpoint, 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 over the course of the study.

We expect to complete enrollment in the RewinD-LB Trial during the second quarter of 2024 and to report initial results from the placebo-controlled portion of the study during the fourth quarter of 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, has been agreed upon with the FDA.

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.

Financial Summary

As of December 31, 2023, we had cash and cash equivalents of approximately $7.8 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 December 31, 2023 was $54.4 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 since inception. Our net loss was $2.2 million and $5.8 million in the years ended December 31, 2023 and December 31, 2022, respectively. We expect our expenses will increase in connection with our ongoing activities, as we:

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

As reported in our Annual Report, based on our then-current operating plan, we determined that our cash and cash equivalents on hand as of December 31, 2023, along with the remaining funds expected to be received from the NIA Grant, would not be sufficient to allow us to fund our current operations and continue as a going concern through at least one year from the date of the issuance of our consolidated financial statements.

On March 28, 2024, we entered into the Purchase Agreement with certain purchasers named therein related to 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 for the 2024 Private Placement were approximately $50.0 million, before deducting offering fees and expenses, and up to an additional approximately $99.4 million in gross proceeds if the Series A Warrants are fully exercised for cash. The 2024 Private Placement closed on April 1, 2024, after the date of the financial information included in this registration statement. Accordingly, except as otherwise indicated, the information contained in this Management's Discussion and Analysis of Financial Condition and Results of Operations, including information regarding our liquidity, capital resources and cash runway, does not reflect the anticipated consummation of, or our receipt of proceeds from, the 2024 Private Placement. However, based on our current operating plan, we believe the upfront proceeds from the 2024 Private Placement, combined with our other cash and cash equivalents as of December 31, 2023, and the remaining funds to be received from the NIA Grant, will enable us to fund our operating expenses for at least twelve months from the date of this prospectus.

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 NIA Grant. Funding from the NIA Grant is recognized as grant revenue as the qualifying expenses related thereto are incurred. As of December 31, 2023, $7.1 million of grant funding was recognized as revenue, of which $6.2 million has been received and the remaining $0.9 million has been recorded as grant receivable. As the NIA Grant was initially awarded in January 2023, there was no grant revenue in the year ended December 31, 2022.

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, which recently initiated a Phase 2b clinical trial for treatment of subjects with DLB. Personnel or other operating expenses incurred for our research and development programs primarily relate to salaries and benefits, stock-based compensation, and facility expenses.

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

General and Administrative Expenses

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

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

Other Income (Expense)

Other income (expense) consists of interest earned on our cash and cash equivalents and the change in fair value of the previously outstanding EIP Convertible Notes.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations:

	December 31,			
	2023	**2022**	**$ Change**	**% Change**
Grant revenue	$ 7,144,872	$ -	$ 7,144,872	100%
Operating expenses:				
Research and development	8,438,499	1,336,469	7,102,030	531%
General and administrative	6,519,268	2,139,065	4,380,203	205%
Loss from operations	(7,812,895)	(3,475,534)	(4,337,361)	125%
Other income (expense):				
Other income (expense)	5,421,592	(2,389,152)	7,810,744	-327%
Interest income	219,430	62,226	157,204	253%
Interest expense	-	(587)	587	-100%
Total other income (expense)	5,641,022	(2,327,513)	7,968,535	-342%
Net loss	$ (2,171,873)	$ (5,803,047)	$ 3,631,174	-63%

Grant Revenue

Grant revenue was $7.1 million for the year ended December 31, 2023 which was a result of services performed during the year ended December 31, 2023 related to the $21.0 million grant awarded to us by the NIA in January 2023 to support a Phase 2b study of neflamapimod in DLB. At December 31, 2023, we had a receivable of $0.9 million for expenses incurred but not yet refunded by the NIA. As the NIA Grant was initially awarded in January 2023, there was no grant revenue in 2022.

Research and Development Expenses

Research and development expenses were $8.4 million for the year ended December 31, 2023, compared to $1.3 million for the year ended December 31, 2022. The increase of $7.1 million was primarily due to our DLB Phase 2b trial beginning in the first quarter of 2023 resulting in an increase in outsourced CRO and related site expenses.

General and Administrative Expenses

General and administrative expenses were $6.5 million for the year ended December 31, 2023, compared to $2.1 million for the year ended December 31, 2022. The increase of $4.4 million was primarily due to the Merger and public company related costs. The drivers of the increase were outsourced accounting/audit fees of $1.3 million, insurance costs of $1.0 million (including a one-time cost related to the merger of $0.8 million), headcount costs of $0.8 million, and investor/public relations costs of $0.7 million.

Other Income (Expense)

Other income (expense) was $5.4 million for the year ended December 31, 2023, compared to $(2.4) million for the year ended December 31, 2022. The amount for the year ended December 31, 2022 was driven by an increase in the estimated fair value of the Convertible Notes while the increase in the year ended December 31, 2023 was driven by the stock price on the date of conversion as a result of the Merger. For additional information regarding the valuation and conversion of the Convertible Notes, see "—Critical Accounting Policies and Estimates – Valuation of Convertible Notes," below.

Interest income

Interest income was $0.2 million and $0.1 million for the years ended December 31, 2023 and 2022, respectively. The increase was primarily due to higher interest earned as a result of an increased cash equivalents balance.

Liquidity and Capital Resources

Capital Requirements

From the date of our inception through December 31, 2023, our operations had primarily been financed through the issuance of common stock, convertible preferred stock and convertible debt financings. As of December 31, 2023, we had approximately $7.8 million of cash and cash equivalents. We have not generated positive cash flows from operations and as of December 31, 2023, we had an accumulated deficit of approximately $54.4 million. In January 2023, we were awarded a $21.0 million grant from the NIA to support the Phase 2b study of neflamapimod in DLB, which is expected to be received over a three-year period. As of December 31, 2023, total cash funding of $6.2 million had been received from the NIA Grant.

In addition, we are party to our 2022 Sales Agreement with BTIG LLC ("BTIG"). The 2022 Sales Agreement is an "at-the-market" sales agreement pursuant to which we may, from time to time and through BTIG as our agent, sell up to an aggregate of $20.0 million in shares of common stock by any permissible method deemed an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. As of the date of this registration statement, however, we have not sold any shares pursuant to the 2022 Sales Agreement.

On March 28, 2024, we entered into a securities purchase agreement with certain purchasers named therein related to 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 2024 Private Placement closed on April 1, 2024. 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.

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations within one year of the issuance date of our financial statements for the period ended December 31, 2023, raise substantial doubt about our ability to continue as a going concern.

Any product candidates we may develop may never achieve commercialization, and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In addition, we expect to incur costs associated with operating as a public company. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, costs related to clinical research, manufacturing and development services; compensation and related expenses; costs relating to the build-out of our headquarters, other offices and laboratories; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; manufacturing costs; legal and other regulatory expenses and general overhead costs.

As of the date of our Annual Report, based on our then current operating plan, we determined that our existing cash and cash equivalents on hand as of December 31, 2023, along with the remaining funds expected to be received from the NIA Grant (but without giving effect to the proceeds from the 2024 Private Placement), would not be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least one year from the date of the issuance of our Annual Report on Form 10-K for the year ended December 31, 2023. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through a debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs, including our development or commercialization activities for neflamapimod. We might also be required to seek funds through arrangements with third parties that require us to relinquish certain of our rights to neflamapimod or otherwise agree to terms unfavorable to us.

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

- the enrollment, progress, timing, costs and results of the RewinD-LB Trial, as well as additional development plans for neflamapimod in other disease indications, such as Recovery after Anterior Circulation 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

	December 31,	
	2023	**2022**
Net cash used in operating activities	$ (7,449,847)	$ (2,572,759)
Net cash provided by financing activities	11,149,114	-
Net increase (decrease) in cash and cash equivalents	$ 3,699,267	$ (2,572,759)

Operating Activities

For the year ended December 31, 2023, cash used in operating activities was $7.4 million. The net cash outflow from operations primarily resulted from net loss of $2.2 million which included a $5.4 million non-cash gain due to a change in fair value of convertible debt and changes in operating assets and liabilities of $0.3 million, offset by a non-cash charge of $0.4 million for stock-based compensation.

For the year ended December 31, 2022, cash used in operating activities was $2.6 million. The net cash outflow from operations primarily resulted from net loss of $5.8 million and change in fair value of convertible debt of $2.4 million, offset by a non-cash charge of $0.3 million for stock-based compensation, $0.1 million of capital in lieu of executive compensation and changes in operating assets and liabilities of $0.4 million.

Financing Activities

For the year ended December 31, 2023, net cash provided by financing activities was $11.1 million. The net cash provided by financing activities primarily resulted from the net assets assumed in connection with the reverse recapitalization and sale of common stock offset by the payment of offering costs.

Investing Activities

We did not have any cash provided by or used in investing activities for the years ended December 31, 2023 or 2022.

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 Polices and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. We believe the following are our more significant estimates and judgments used in the preparation of our financial statements.

Research and Development Costs

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

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

If we underestimate or overestimate the level of services performed or the costs of these services, actual expenses could differ from estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

Stock-based Compensation

Stock-based compensation for employee and non-employee awards is measured on the grant date based on the fair value of the award and recognized on a straight-line basis over the requisite service period. The fair value of stock options to purchase common stock are measured using the Black-Scholes option pricing model. We account for forfeitures as they occur. The fair value of stock options is determined by us using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

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

Expected Volatility. We have limited information on the volatility of common stock as the shares were not actively traded on any public markets until recently. As such, expected volatility is derived from the historical stock volatilities of comparable peer public companies within our industry. These companies are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

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

Expected Dividend Rate. The expected dividend is zero as we have not paid, nor do we anticipate paying, any dividends on our stock options in the foreseeable future.

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

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

Valuation of Convertible Notes

The fair value of the Convertible Notes as of December 31, 2022 were estimated as the combination of a zero-coupon bond and a call option. The combined values for each of the Convertible Notes as of December 31, 2022 were then weighted by the probability of completing a financing or reverse merger. This approach resulted in the classification of the Convertible Notes as of December 31, 2022 as Level 3 of the fair value hierarchy (see Note 9 to the consolidated financial statements included elsewhere in this prospectus). The assumptions utilized to value the 2020 Notes and the 2021 Notes as of December 31, 2022 were an estimated term of 0.94 years, volatility of 80.0% and a market yield of 55.2%.

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

Recently Issued Accounting Pronouncements

The information in *Note 3, Basis of Presentation and Summary of Significant Accounting Policies* to our consolidated financial statements set forth elsewhere in this prospectus is incorporated herein by reference.

BUSINESS

Overview

We are a clinical-stage biotechnology company focused on developing treatments for age-related neurologic disorders. We are currently focused on the development of our lead drug candidate, neflamapimod, an investigational, orally administered, small molecule brain penetrant that inhibits p38α in the neurons (nerve cells) within the brains of people with neurodegenerative diseases. Neflamapimod has the potential to treat and improve synaptic dysfunction, the reversible aspect of the underlying disease processes 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 DLB funded by a $21.0 million grant from the NIA. We expect to complete enrollment in the RewinD-LB Trial during the second quarter of 2024 and to report initial results from the placebo-controlled portion of the study during the fourth quarter of 2024.

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 p38α in the neurons (nerve cells) within the brains of people with neurodegenerative diseases is believed to impair how neurons communicate through synapses (the connections between neurons). This impairment, termed synaptic dysfunction, leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in neuronal loss that leads to devastating disabilities, 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 p38α 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 has initiated a Phase 2b clinical evaluation (our ongoing RewinD-LB Trial), from which we expect initial results before the end of 2024. The clinical symptoms in DLB are most directly linked to synaptic dysfunction in cholinergic neurons (neurons producing the neurotransmitter acetylcholine) in a part of the brain named the basal forebrain. 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. Following earlier clinical studies demonstrating blood-brain-barrier penetration, target (p38α) 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 that includes all patients randomized into the study that had at least one measurement of the endpoint analyzed. In addition, in a secondary analysis, neflamapimod demonstrated statistically significant improvement compared to placebo in a battery of cognitive tests, particularly with respect to tests that measured attention.

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 efficacy and identified the DLB patient population most responsive to neflamapimod treatment. In these analyses, the results were stratified by pre-treatment levels of plasma ptau181, which recent scientific literature has identified as a biomarker to differentiate DLB patients with AD-associated co-pathology – a form of mixed dementia which we sometimes refer to as "DLB+AD" – from DLB patients without AD-associated co-pathology – which we sometimes refer to as "pure DLB." In pure DLB patients, who generally represent early-stage patients with limited neurodegeneration in the hippocampus, the treatment response to neflamapimod in the AscenD-LB Trial was substantial (Cohen's *d* effect size ≥ 0.7 and statistically significant vs. placebo on the CDR-SB, TUG, cognitive tests of attention and working memory) and greater than the overall patient population. In a February 2024 publication in the *Journal of Prevention of Alzheimer's Disease*, results from our prior clinical trials of neflamapimod in AD and DLB were integrated to show not only the demonstrated effects of neflamapimod on cognition and function, but on other biomarkers such as EEG and brain volume and functional connectivity in the basal forebrain.

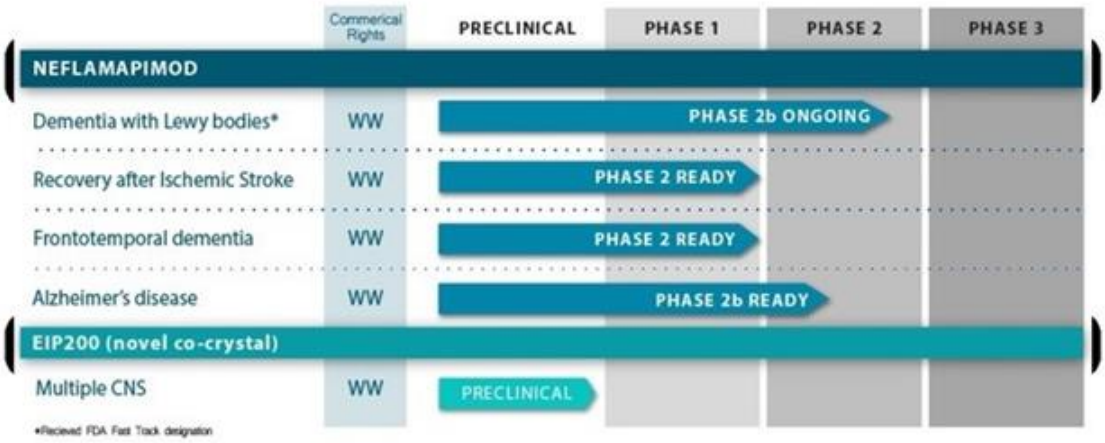
Our ongoing RewinD-LB Trial is a double-blind, placebo-controlled, 16-week Phase 2b study in 160 patients with pure DLB funded by a $21.0 million grant from the NIA. The trial is intended to confirm the efficacy findings from the AscenD-LB Trial and definitively demonstrate proof-of-concept. We have utilized our subsequent analyses of the AscenD-LB 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 will exclude patients with Alzheimer's disease related co-pathology as evaluated by plasma ptau181 levels (i.e., the study will only enroll patients with pure DLB) and, to enrich for such patients, the global CDR-SB score at entry will be limited to 0.5 or 1.0. Together with additional modifications to the Phase 2a design related to dosing regimen and primary endpoint, 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 over the course of the study.

We expect to complete enrollment in the RewinD-LB Trial during the second quarter of 2024 and to report initial results from the placebo-controlled portion of the study during the fourth quarter of 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, has been agreed upon with the FDA.

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.

Our Pipeline

Set forth below is a table presenting our clinical pipeline:



Our Team

We have assembled a diverse team of experienced company builders and drug developers, complemented by an experienced Board and world-class scientific advisors. This group shares a long-term commitment to execute our strategy, advance the development of neflamapimod, and improve treatment outcomes and quality of life for patients suffering from age-related neurologic disorders. Moreover, we benefit from the significant pharmaceutical development experience of our management team members and directors, several of whom have worked on neflamapimod in the past at Vertex and are well acquainted with the unique properties of the compound for application in DLB and other potential target indications.

- *Our Co-Founder, President and Chief Executive Officer, John Alam, M.D.*, is a biotech industry veteran with more than 30 years' experience and is an industry leader in translational medicine. He has a proven track record of creating value through clinical development success, including having played major roles during the clinical development of five innovative drugs that are now on the market, and is an emerging drug development leader in neurodegenerative diseases, including having been the global head of all R&D activities directed towards neurodegenerative diseases at Sanofi S.A. (Nasdaq: SNY), a top ten global pharmaceutical company. Dr. Alam also has direct experience with neflamapimod from his time at Vertex, where he was Executive Vice President, Medicines Development and Chief Medical Officer. Dr. Alam also led the clinical development of Biogen's first approved drug for the treatment of multiple sclerosis, Avonex.

- *Our Co-Founder and Director, Dr. Sylvie Grégoire, PharmD.,* is also an industry veteran with more than 30 years' experience who previously held executive leadership posts in several multinational life sciences firms. Dr. Grégoire has extensive experience with corporate governance and board operations and is currently also on the board of directors at of two public life sciences companies, Novo Nordisk A/S (NYSE: NVO) and Revvity (Nasdaq: RVTY) (formerly known as PerkinElmer, Inc. (NYSE: PKI)), and one private company, F2G; and she previously was chair of Corvidia Therapeutics (acquired by Novo Nordisk), and member of the board of directors of ViFor Pharma (acquired by CSL) and Cubist Pharmaceuticals (acquired by Merck).

- *The Chair of our Board, Joshua S. Boger, Ph.D.*, is an industry veteran who has served in multiple scientific and business leadership roles during his multi-decade career. Dr. Boger founded Vertex in 1989 and served as its Chief Executive Officer from 1992 until 2009, and currently serves as the Executive Chairman of Alkeus Pharmaceuticals. Prior to founding Vertex, Dr. Boger was Senior Director of Basic Chemistry at Merck Sharp & Dohme Research Laboratories in Rahway, NJ, where he headed both the Departments of Biophysical Chemistry and Medicinal Chemistry of Immunology & Inflammation.

- *Our Chief Financial Officer, William Tanner, Ph.D.*, through his more than 20 years' experience as a healthcare research analyst at well recognized investment banks, has expertise and relevant industry experience.

- *Our Chief Operating Officer, Robert J. Cobuzzi, Jr., Ph.D.*, has over 25 years of cross-functional executive and operational leadership experience in the pharmaceutical and biotechnology industries across the areas of corporate development, research & development, and operations, at Endo International Plc, Adolor Corporation, Diffusion Pharmaceuticals, Centocor and AstraMerck. Dr. Cobuzzi also currently serves as a Venture Partner for Sunstone Life Science Ventures and also is Chairman of Sunstone's Business Development Advisory Board.

- *Our SVP of Clinical Development, Kelly Blackburn, MHA,* has more than 30 years of experience in clinical development operations, including senior management positions at aTyr Pharma and Vertex where she held senior global clinical operational responsibility for three major novel therapeutics: Kalydeco® for the treatment of cystic fibrosis, Incivek® for hepatitis C, and Velcade® for multiple myeloma.

- In addition, to provide a strong scientific underpinning for the neflamapimod program, we have surrounded ourselves with thought leaders in the fields of cell biology, intracellular signal transduction, neurotherapeutics, and translational neuroscience. Our SAB is chaired by Dr. Ole Isacson, who serves as Professor of Neurology at Harvard Medical School and is a Founding Director of the Neuroregeneration Research Institute at McLean Hospital. Other members of our SAB include Dr. Lewis Cantley, Professor of Cell Biology at the Dana Farber Cancer Institute, and who previously served as the Director of the Sandra and Edward Meyer Cancer Center at the Weill Cornell Medical Center; Dr. Jeffrey Cummings is the Joy Chambers-Grundy Professor of Brain Science at the UNLV Integrated School of Health Sciences and Director of the Chambers-Grundy Center for Transformative Neuroscience, and Director Emeritus of the Cleveland Clinic Lou Ruvo Center for Brain Health and Professor at the Cleveland Clinic Lerner College of Medicine of Case Western University; and Dr. Heidi McBride, Canada Research Chair in Mitochondrial Cell Biology and as Professor in the Department of Neurology and Neurosurgery at McGill University.

Our Strategy

Our mission is to develop and commercialize innovative medicines that change the course of the disease of patients who suffer from age-related neurologic disorders.

The key elements of our strategy are:

- *Advance clinical development of neflamapimod for treatment of DLB with a focus on moving the program through to Phase 3 initiation in mid-2025*. We initiated our Phase 2b RewinD-LB Trial in the second quarter of 2023 and anticipate completing enrollment in the second quarter of 2024. The efficacy data, which would come at the end of the four-month placebo-controlled portion of the trial, are expected in the fourth quarter of 2024. With those results in hand, we plan to meet with the FDA in an end-of-Phase 2 meeting to finalize the design of a single 24-week treatment duration Phase 3 clinical trial, which we are targeting to initiate in mid-2025. As the design of the Phase 3 clinical trial will largely replicate the RewinD-LB Trial design, we believe that success in the RewinD-LB Trial will be a meaningful predictor of the potential for a successful clinical outcome in our planned Phase 3 trial.

- *Advance clinical development of neflamapimod for other disease indications*. Neflamapimod's mechanism of action with respect to treating neuro-inflammation and, more specifically, cholinergic dysfunction and degeneration provides opportunities to advance our drug in a range of neurologic disorders, in addition to DLB, in which targeting and treating BFC dysfunction and degeneration would be expected to provide substantial clinical benefit. Our anticipated second indication is as a three-month treatment following ischemic stroke to promote neurologic recovery, particularly of motor function. A potential third indication is as disease-modifying treatment early-stage AD, when the BFC degeneration is a major driver of disease progression. In addition, we believe there is strong scientific basis for evaluating neflamapimod in certain forms of frontotemporal dementia.

- *Commercialize neflamapimod ourselves and/or in collaboration with one or more partners*. If neflamapimod receives regulatory approval, we intend to be prepared to commercialize as soon as practicable in the market(s) where it is first approved, if at all, which we expect to be in North America and/or Europe. In the future, we may seek partners to seek approval and commercialize our products in other regions.

- *Expand our pipeline through in-licensing and acquisitions*. In the future, we intend to leverage our expertise in drug development and business development, as well as our understanding of translational neuroscience with respect to synaptic dysfunction, to opportunistically evaluate product candidates that are complementary to neflamapimod in our pursuit of novel therapies for DLB, AD and other age-related neurologic disorders.

Neflamapimod in Dementia with Lewy Bodies

Our Approach

Our approach is based on an understanding of the mechanism by which neuroinflammation leads to the initiation and establishment of the neurodegenerative process. The process of neurodegeneration starts with dysfunction of synapses, i.e., the interconnections between neurons. Treating synaptic dysfunction has emerged as a major therapeutic objective to address progression of neurodegenerative diseases, particularly in the early stages prior to the onset of significant cell death. Importantly, in animal models, while neurodegeneration is irreversible, synaptic dysfunction has been observed to be reversible. In addition, even in animal models of rapidly progressive neurodegeneration (e.g., prion disease), interventions that reverse synaptic dysfunction both improve function and "arrest" the neurodegenerative process. Thus, therapeutic interventions that target synaptic dysfunction have the potential to both reverse and slow disease progression in the early stages of neurodegenerative dementias.

The basal forebrain, and specifically nerve cells producing the neurotransmitter acetylcholine (i.e., "cholinergic neurons"), play critical roles in controlling and optimizing a wide range of cognitive, motor, and visual tasks. Synaptic dysfunction in the basal forebrain cholinergic system is the primary pathogenic driver of disease expression and progression of DLB. Basal forebrain cholinergic dysfunction also plays a major role in disease progression in the early stages of AD, and basal forebrain cholinergic dysfunction is rate limiting for optimal recovery after ischemic stroke.

In collaborative work conducted with the New York University Langone Medical Center, and as published in the journal *Nature Communications*, we have demonstrated that neflamapimod targets the specific molecular mechanisms underlying basal forebrain cholinergic dysfunction, and eventually degeneration, and, as discussed in subsequent sections, can successfully reverse disease progression in animals with basal forebrain cholinergic dysfunction and degeneration.

Capitalizing on Our Strengths

We believe that the following competitive strengths will allow us to execute on our mission to develop and commercialize neflamapimod as a disease modifying innovative drug treatment for patients who suffer from DLB and other neuro-inflammatory age-related neurologic disorders:

- *Our approach to degenerative diseases of the brain is highly differentiated and has the potential to be the first to market specific drug therapy for DLB*. Our approach focuses on reducing the impact of neuroinflammation. Neuroinflammation is directly linked with the initiation of the neurodegenerative process through synaptic dysfunction, which results in a reduction or elimination of the ability of the affected neurons to transfer information. Neflamapimod targets neuro-inflammation and, particularly, the molecular mechanisms within neurons that lead to synaptic dysfunction, thereby both improving cognitive function and slowing down the process that leads to neuronal loss. Currently, there are no approved therapies for DLB and there is limited drug development in this area, with neflamapimod being, to our knowledge, the only disease-modifying approach that has demonstrated significant improvements on clinical outcome measures in a clinical trial in DLB.

- *Neflamapimod has the potential to meet a significant unmet medical need and achieve substantial commercial return*. We believe that neflamapimod can address the high unmet medical need with respect to both the cognitive and motor aspects of DLB. DLB is the third most common chronic degenerative disease of the brain (after Alzheimer's disease and Parkinson's disease), with an estimated 700,000 individuals with the disease in each of the U.S. and European Union. Despite this prevalence and high unmet medical need, there are currently no FDA or EMA approved treatments for DLB. Further, patients are referred to neurologists to treat the disease. The specialty nature of neflamapimod, if approved, combined with the prevalence of the disease should present a significant commercial opportunity, including through reimbursement, based on the impact on patients' quality of life and ability to function, reduction of caregiver burden and reduction of health care costs associated with DLB, among other factors.

- *Neflamapimod has the potential to improve cognitive and motor function (i.e., restore function), providing the opportunity to demonstrate clinical efficacy in Phase 2 and, if successful, provide a meaningful predictor of the potential for a successful clinical outcome in Phase 3*. A major challenge in developing effective drug treatments for chronic neurodegenerative diseases, particularly AD, has been that approaches to date do not show improvement in disease outcomes in Phase 2 clinical trials (i.e., trials of less than six-month duration). Instead, demonstration of clinical efficacy depends on clinical trial duration of at least 12 to 18 months and large subject numbers (~1,000 or more), effectively requiring Phase 3 trials designed to show an effect of slowing disease progression relative to placebo treatment. As a result, Phase 2 clinical trials data may not provide a meaningful predictor of the potential for a successful clinical outcome in Phase 3 in AD. In contrast, in early-stage DLB, because there is less extensive neuronal loss and fixed (i.e., irreversible) clinical deficits compared to AD, there is the potential to reverse disease progression and improve function in Phase 2 clinical trials. Neflamapimod has previously been shown to reverse disease progression and restore function in preclinical studies and has demonstrated improvement as compared to placebo on clinically meaningful outcomes in a 16-week Phase 2a clinical trial, particularly in patients with pure DLB. If the results of our AscenD-LB Trial are confirmed in the ongoing RewinD-LB Trial (the placebo-controlled portion of which will also be of 16 weeks duration) with a statistically significant difference between placebo and neflamapimod treatment on the primary endpoint, we believe we will have demonstrated proof-of-concept (i.e., have established the neflamapimod is efficacious in the treatment of DLB). In addition, based on discussions we have had with the FDA, and pending confirmation in an end-of-phase 2 meeting with the FDA that we plan to have after Phase 2b, approval for neflamapimod could be obtained with the conduct of a single 24-week treatment duration Phase 3 study involving a few hundred subjects, although there can be no assurances. As the design of the Phase 3 clinical trial will largely replicate the RewinD-LB Trial design, we believe that success in the RewinD-LB Trial will be a meaningful predictor of the potential for a successful clinical outcome in our planned Phase 3 trial. See section titled “Item 1A. Risk Factors - Risks Related to the Company’s Product Development and Regulatory Approval” for a further description of these factors and uncertainties.

- *Neflamapimod has been extensively tested in animals and humans*. The safety and tolerability profile has been extensively evaluated and is well understood. Specifically, long-term toxicology studies of neflamapimod have been completed and the drug has been administered to over 300 volunteers and subjects to date (including over 150 subjects in Phase 2 clinical trials in either DLB or AD), some of whom have received up to 30 times the dose we are using in our ongoing RewinD-LB Trial and currently plan to utilize in our planned Phase 3 trial.

DLB Background

Unmet Medical Need

Dementia with Lewy bodies is the second most common neurodegenerative dementia (after AD), representing 10-20% of the dementia population. The Lewy Body Dementia Association estimates there are 1.4 million individuals in the United States affected with Lewy body dementia, which includes both PDD and non-Parkinson’s DLB. As non-Parkinson’s DLB and PDD are prevalent in the United States at an approximate ratio of 1:1, there are approximately 700,000 individuals with DLB in the United States. Furthermore, the prevalence in European countries is similar to that in the United States, and so we believe there also are approximately 700,000 individuals with DLB in the European Union as well. Despite this prevalence, there are currently no approved treatments specifically for DLB in the U.S. or the European Union.

DLB is characterized by progressive dementia and fluctuating cognition (particularly deficits in attention), visual hallucination, motor dysfunction (disturbances in gait and balance) and sleep disturbances. With respect to life expectancy, in a large cohort of DLB and AD cases (251 DLB, 222 AD), after controlling for age at diagnosis, comorbidity, and antipsychotic prescribing, the survival for DLB was shorter compared to AD, with a median (average) survival of less than four years with DLB (3.3 years for males and 4.0 for females), as compared to nearly seven years with AD (6.7 years for males and 7.0 years for females). Antecedent to death, the time progression to severe dementia is also shorter by nearly two years with DLB compared to AD.

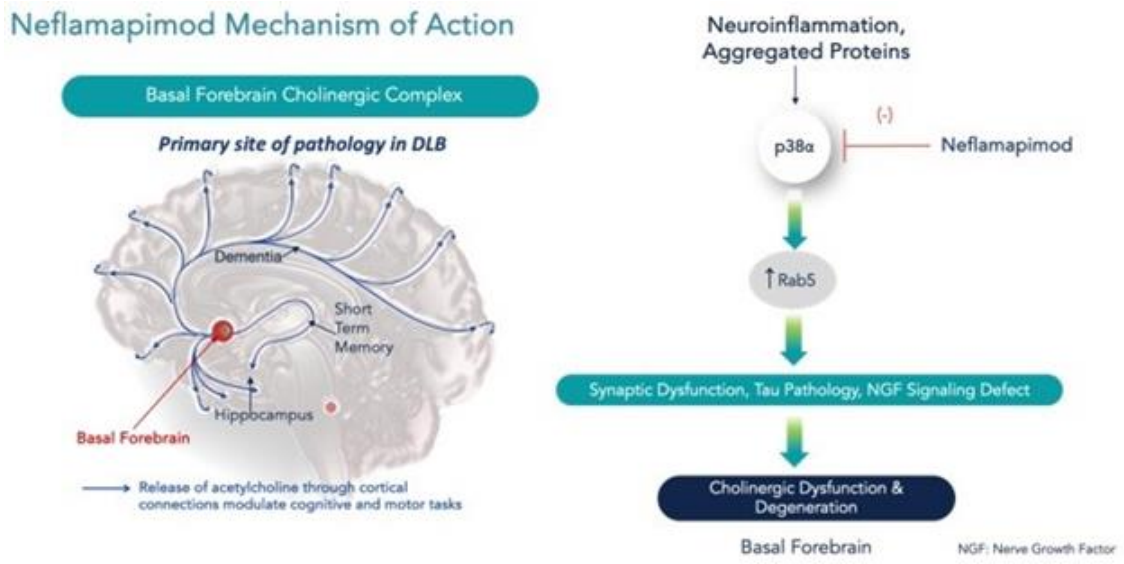
Separate from survival and progression to severe disease, even in the mild-to-moderate stages, with deficits occurring in both cognitive and motor function, the disease burden with respect to quality of life and caregiver burden, is greater in DLB than in AD. Furthermore, patients with DLB are more frequently admitted to general hospitals and utilize inpatient care to a substantially higher degree than do those with AD or the general elderly population. Most importantly, in a large prospective study, mild dementia patients with DLB were admitted to a nursing home after only a median of 1.8 years from presentation and diagnosis, nearly two years shorter than the 3.7 years in the AD group.

Accordingly, DLB in afflicted persons often progresses quickly and severely impacts not only the daily lives of patients suffering from the disease but that of their caregivers. There are currently no disease-modifying treatments available for DLB, so management of DLB currently focuses on relief of symptoms, including its cognitive and parkinsonian (e.g., tremor) manifestations. No approaches have been shown to clinically slow neuronal loss or prevent cognitive decline, and there are no approved therapies for treating the underlying disease process or disease-modifying drugs in Phase 3 clinical trials. Though not approved for DLB, cholinesterase inhibitors are used in its management, with some limited and transient improvement in cognition and a reduction in the frequency and severity of visual hallucinations. However, despite treatment with cholinesterase inhibitors, the cognitive and functional impairments progress rapidly, caregiver burden remains high, and new treatments are needed for these patients. With respect to the motor component of DLB, dopaminergic medications (e.g., carbidopa/levodopa) work less well in DLB as compared to PD and patients with DLB generally have a limited response to these medications, which are in any case poorly tolerated in this patient population; a reason for the poor response is that DLB is primarily a disease of the cholinergic system, rather than the dopaminergic system.

Scientific Rationale

Recent evidence indicates that the primary pathology in DLB is in the basal forebrain cholinergic system, dysfunction and degeneration of which drives neurodegeneration in other regions of the brain. A series of publications, largely from the laboratories and colleagues of Prof. William Mobley at UCSD and Prof. Ralph A. Nixon at NYU Langone and the Nathan Kline Psychiatric Institute, have defined the molecular mechanisms that lead to neurodegeneration of cholinergic neurons. As shown in the figure below, the cholinergic degeneration is believed to result from inflammation and various aggregated proteins that lead to aberrant activation of the protein Rab5, a master regulator of endocytosis and endosomal trafficking, further leading to impaired retrograde axonal transport and a block in NGF signaling from the synapses at the ends of nerve fibers (or "axons") back to cell body of the cholinergic neuron in the basal forebrain. The resulting loss of support of neuronal health that NGF provides is then believed to lead to dysfunction, and, eventually, degeneration of cholinergic neurons, which are particularly vulnerable to this pathogenic process because of their very long fibers.

Molecular Mechanisms Underlying Cholinergic Neurodegeneration in DLB and Point of Intervention for Neflamapimod



Early-stage patients with pure DLB (i.e., the ~50% of patients without AD-related co-pathology assessed by biomarkers) have relatively limited neurodegeneration and neuronal loss in the cortical regions of the brains, including and particularly in the hippocampus. Moreover, based on a range of animal and human pathology studies, the cholinergic degenerative process in the basal forebrain is believed to be reversible. The cholinergic neurons in that region of the brain do not die, rather they stop functioning normally (i.e., stop producing acetylcholine) and atrophy, or shrink in size. However, as those neurons are still alive, with successful pharmacological treatment they can be rescued and the disease process reversed.

Neflamapimod was hypothesized to reduce Rab5 protein activity – a key therapeutic target in this pathogenic model for cholinergic degeneration in DLB – because of scientific literature showing that the immediate target of neflamapimod, p38α kinase, is the major activator of Rab5. Based on that hypothesis, neflamapimod was evaluated in a preclinical study in an animal model intended to evaluate neflamapimod's effects on basal forebrain cholinergic atrophy and, later, in our Phase 2a AscenD-LB Trial in patients with DLB. We believe that the results of these studies, through demonstration of reduction in Rab5 activity and reversal cholinergic dysfunction & degeneration, demonstrate neflamapimod's potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes in the basal forebrain cholinergic system that cause disease in DLB. We also have obtained and published results from a pilot clinical study in patients with early AD that demonstrate neflamapimod treatment increases the volume of the basal forebrain, as well its functional connectivity to the cortex, as assessed by structural and functional MRI, respectively.

Clinical Development Plan

AscenD-LB Trial: Our Completed Phase 2a Trial in Dementia with Lewy Bodies

The AscenD-LB Trial was a Phase 2a double-blind, placebo-controlled, 16-week treatment, exploratory clinical trial of neflamapimod in mild-to-moderate DLB conducted at 22 centers in the United States and two centers in the Netherlands. 91 subjects were enrolled between October 2019 and March 2020 and randomized to receive 40 mg neflamapimod capsules or matching placebo capsules (randomized 1:1) for 16 weeks. The dosing regimen was based on weight, with trial participants weighing less than 80 kg receiving capsules BID and those weighing greater than or equal to 80 kg receiving capsules TID. All subjects had to have already been receiving oral cholinesterase inhibitor therapy for at least three months (stable dose for greater than six weeks) and continued such therapy without dose modification during the trial.

The AscenD-LB Trial was an exploratory clinical trial designed to evaluate the effects of neflamapimod against a range of clinical endpoints. In the primary analysis of the AscenD-LB Trial, which included all patients enrolled and evaluated for treatment effects, neflamapimod demonstrated improvement compared to placebo in dementia severity (assessed by CDR-SB, p=0.023 vs. placebo) and functional mobility (gait or walking ability as assessed by the TUG test, p=0.044 vs. placebo). In additional analyses, at the highest dose (40mg TID), significant improvement on a cognitive test battery, or NTB, was evident as compared to placebo (p=0.049); however, significant improvement compared to placebo on the NTB was not evident in the primary analysis. In addition, encouraging positive trends on the ten-item Neuropsychiatric Inventory were seen, particularly with respect to visual hallucinations, where a significant reduction in frequency relative to placebo was seen.

This primary analysis of the AscenD-LB Trial data showing neflamapimod significantly improved dementia severity and motor function was published in the major scientific journal *Nature Communications* in September 2022.

Primary Analysis of Major Efficacy Endpoints in AscenD-LB Trial of Neflamapimod in DLB

		40mg BID + 40mg TID		40mg TID	
		Mean difference vs. placebo (95% CI)	*p-value*	*Mean difference vs. placebo (95% CI)*	*p-value*
Dementia Severity	Clinical Dementia Rating Sum of Boxes (CDR-SB)	-0.45 (-0.83, -0.06)	0.023	-0.56 (-0.96, -0.16)	0.007
Cognitive Testing	*Neuropsychological Test Battery (NTB) Composite z-score*	0.04 (-0.11, 0.19)	>0.2	0.17 (0.00, 0.35)	0.049
	Attention Composite z-score	0.14 (-0.06, 0.35)	0.17	0.28 (0.04, 0.51)	0.023
Motor Function	Timed and Go Test (TUG)	-1.4 (-2.7, -0.1)	0.044	-1.4 (-2.6, -0.2)	0.024

On-study (all time-points) results; change from baseline analysis utilizing Mixed Model for Repeated Measures. Number of participants: 41 for placebo, 20 each for 40mg BID and 40mg TID.

We believe the lack of significant effect in the primary analysis on the cognitive testing (NTB) results are attributable to the combination of (1) the inclusion of subjects receiving the lower, 40 mg BID dose of neflamapimod, a dose that did not achieve targeted therapeutic blood drug concentrations, and (2) “ceiling effects”, (i.e. that patients with disease have exogenous limits on how much they can improve on a cognitive test) resulting from two separate potential causes. First, all patients in the study were receiving cholinesterase inhibitor therapy, which is known to improve outcomes on cognitive testing in patients with DLB; that is, with having received benefit with cholinesterase inhibitor therapy, there was a limit to how much better perform with neflamapimod treatment, particularly with low dose neflamapimod treatment. Second, the deficits in executive function at baseline were very mild and, as a result, the tests evaluating executive function (two of six in the NTB) could not have demonstrated an effect.

Based on recent scientific literature demonstrating that DLB subjects with abnormally elevated plasma ptau181 (tau protein phosphorylated at residue 181) have AD associated co-pathology (specifically amyloid plaque and/or tau pathology by PET scan or CSF analysis), additional pre-specified analyses of the AscenD-LB data stratified by baseline plasma ptau181 were conducted and identified the pure DLB patient population as the optimal patient population for the RewinD-LB Trial and any future phase 3 clinical trials. Compared to subjects with DLB without elevated plasma ptau181 (i.e., with "pure" DLB), subjects with DLB with elevated plasma ptau181 have more extensive neuronal loss (neurodegeneration) and, therefore, would be expected to be less responsive to treatment. As shown in the table below, patients in the AscenD-LB Trial with pure DLB had an average higher treatment response (evaluated by Cohen's *d* effect size), compared to the average response in the overall study, and demonstrated significant improvement in cognitive tests of Attention, the CDR-SB, the TUG test, and in a rest of recognition memory (International Shopping List Test recognition index) with Cohen's *d* treatment effect size that was greater than 0.7 for each of these endpoints, indicating clinical effects that are moderate-to-large in magnitude. By comparison, in published studies in the scientific literature, the cholinesterase inhibitors have Cohen's *d* effect size of approximately 0.3 in the treatment of AD or DLB.

Magnitude of 40mg TID Neflamapimod Treatment Effect vs. Placebo in Overall Patient Population and in the Pure DLB Patient Population) of the AscenD-LB Trial*

	Overall Study Population				Patients With Pure DLB (Plasma ptau181 < cutoff)			
	N= NFMD TID, Placebo	Difference[1] (95% CI)	p-value	Cohen's d Effect size	N= NFMD TID, Placebo	Difference[1] (95% CI)	p-value	Cohen's d Effect size
NTB	19,37	+0.17 (0.00,0.35)	0.049	0.47	11,19	+0.21 (-0.07,0.49)	0.13	0.56
Attention	19,36	+0.28 (0.04,0.51)	0.023	0.41	11,18	+0.42 (0.07,0.78)	0.023	0.78
CDR-SB	20,38	-0.56 (-0.96, -0.16)	0.007	0.31	11,22	-0.60 (-1.04, -0.06)	0.031	0.74
TUG	20,38	-1.4 (-2.6, -0.2)	0.024	0.50	11,20	-3.1 (-4.7, -1.6)	<0.001	0.74
ISLT	20,42	+0.32 (-0.48,1.12)	NS	0.15	11,22	+2.1 (0.0,4.2)	0.053	0.55
ISLT- RECOGNITION	19,39	+0.47 (-0.17,1.11)	0.15	0.17	10,21	+1.4 (0.02,2.5)	0.024	1.0

* By convention the magnitude of a treatment is considered small when the Cohen's *d* effect size between 0.2 and, moderate when it is 0.4 to 0.8 and large when it is 0.8 or greater.

In September 2023, the results of these additional analyses of the AscenD-LB Trial were published in Neurology, the medical journal of the American Academy of Neurology. A subsequent publication in Molecular Neurodegeneration provides a combined evaluation of the findings in the Neurology and Nature Communications articles that makes the case for advancing neflamapimod as a treatment for DLB.

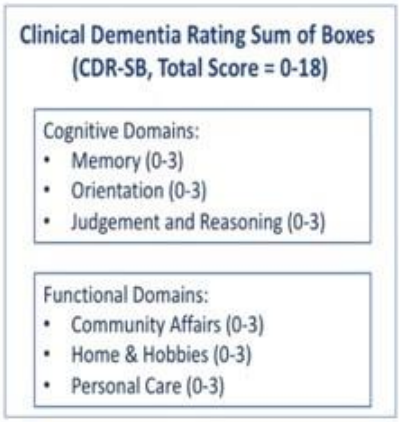
RewinD-LB Trial: Our Ongoing Phase 2b Trial in Dementia with Lewy Bodies

In the second quarter of 2023, we initiated our ongoing RewinD-LB Trial, a Phase 2b clinical trial of neflamapimod in subjects with DLB funded by a $21.0 million grant from the NIA, and, in August 2023, we announced dosing of the first patient in the study. We believe the design of the RewinD-LB Trial has positioned the study for success, as it is based on our findings and learnings from the AscenD-LB Trial, including the following:

- Based on the dose response analysis of the AscenD-LB Trial and observations in prior AD studies, the optimal dose was identified as 40 mg TID, which will be the only dosing regimen used in the RewinD-LB Trial.
- Clinical endpoints that can detect effects on both cognitive and motor function (specifically, CDR-SB and TUG) better distinguish drug treatment from placebo than tests that are purely focused on evaluating cognition. Moreover, in AD, CDR-SB is accepted by regulatory authorities as an approval endpoint. Accordingly, we have chosen CDR-SB as the primary endpoint in the RewinD-LB Trial.
- Subjects with pure DLB (i.e., those without AD co-pathology as evidenced by increased concentrations of ptau181) appear to have a greater response to treatment. Therefore, we have chosen to exclude subjects with elevated (i.e., abnormal) levels of ptau181 in the RewinD-LB Trial. We believe that excluding subjects with abnormal ptau181 substantially increases the statistical power to demonstrate treatment effects in clinical trials of neflamapimod in DLB.

Accordingly, in the RewinD-LB Trial, neflamapimod will be administered orally, 40 mg TID, with a second group receiving matching placebo. Each treatment group will include 80 subjects (enrolling a total of 160 subjects) diagnosed with DLB by consensus criteria, including having an abnormal dopamine transporter scan. Subjects with elevated plasma ptau181 (i.e., having evidence of AD co-pathology) will be excluded. Treatments (neflamapimod or placebo) will be administered for 16 weeks in the main trial (i.e., double-blind, placebo-controlled portion of the study), with a 36-week open label treatment extension for subjects completing the initial 16-weeks of the trial. Following completion of informed consent procedures, subjects will enter the screening phase of the trial. Once eligibility is confirmed and before the first dose of study drug, subjects will be randomly assigned on 1:1 basis to placebo or neflamapimod treatment. Dosing will start on day 1 following completion of all baseline procedures. During the placebo-controlled portion of the trial, subjects will return to the clinic at the end of weeks 2, 4, 8, 12 and 16.

The primary objective of the trial is to demonstrate that neflamapimod, compared with placebo, improves dementia severity, as assessed by change from baseline to week 16 in CDR-SB score. The CDR-SB is designed to assess both cognition and function, and is obtained by clinicians rating the severity of symptoms across 6 domains – memory, orientation, judgment & problem solving, community affairs, home & hobbies, and personal care – after a semi-structured interview with the patient and a reliable informant (e.g. family member) on a 0–3 scale for each domain (total range 0–18, with a higher score indicating worse dementia).



Secondary objectives include further evaluation of the safety and tolerability of neflamapimod and treatment effects on (1) cognition, assessed by a DLB-specific cognitive test battery, (2) motor function, as assessed by the TUG test, and (3) global rating of treatment effect, assessed by the CGIC. Tertiary endpoints will examine whether neflamapimod affects neuropsychiatric outcomes as assessed by the NPI-12, effect on fluctuations in cognition as assessed by the Dementia Cognitive Fluctuations Scale, impact on resting-state EEG (as well alpha-reactivity evaluated by EEG) and in a sub-set of subjects, basal forebrain atrophy assessed by structural MRI.

Sample size was calculated via simulations conducted utilizing the data in the Phase 2a study for the major clinical endpoints in the neflamapimod 40mg TID and placebo groups, generating for each patient a change from baseline for each endpoint at individual visits over the course of the simulated clinical study, and then analyzing the result using the linear mixed effects model for repeated measures that will be utilized to analyze the Phase 2b study. Based on the simulation of 100 clinical trials with 80 patients per treatment group, and assuming a 10% dropout rate, the RewinD-LB Trial has approximately 85% power with the NTB, 95% power with TUG, and greater than 95% power (approaching 100%) with the primary endpoint, CDR-SB, to detect a treatment effect at a significance level of 0.05.

We expect to complete enrollment in the RewinD-LB Trial during the second quarter of 2024 and to report initial results from the placebo-controlled portion of the study during the fourth quarter of 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 has been agreed upon with the FDA.

Planned Phase 3 Development in DLB Based on Success in Phase 2b Clinical Trial

We met with the FDA in January 2020, after completion of the AscenD-LB Trial and availability of the preliminary analysis of the results, in an end-of-phase 2 meeting to discuss potential Phase 3 clinical designs that may support approval of neflamapimod for the treatment of DLB. In that meeting, the FDA stated that a single Phase 3 clinical trial of six months' treatment duration may be sufficient to support approval of neflamapimod if the trial demonstrated robust, clinically meaningful effects on cognition and on either function or a global measure (e.g., CGIC). Based on those discussions, we believe that if the RewinD-LB Trial demonstrates significant effects on the primary CDR-SB endpoint (a clinically meaningful measure of cognition and function), the result would be highly predictive of success in Phase 3, as the Phase 3 clinical trial would be designed to replicate the Phase 2b findings over six months (an additional two months compared to the four months in Phase 2b). Further, the number of subjects to be enrolled in a Phase 3 trial, which at the time of the January 2020 meeting was proposed to be 250 subjects, would be adjusted based on treatment effect size observed in the Phase 2b results to provide >95% statistical power for the primary efficacy endpoint. We are also evaluating CGIC in our planned Phase 2b trial for incorporation as a potential endpoint in the Phase 3 clinical trial. The size of a Phase 3 clinical trial and certain other aspects of the Phase 3 trial (e.g., choice of secondary endpoints) would be discussed with the FDA in a second end-of-phase 2 meeting that we would expect to schedule after the primary efficacy data are available from the ongoing RewinD-LB Trial, which we anticipate being available in the fourth quarter of 2024.

NIA Grant

In January 2023, we were awarded a $21.0 million grant from the NIA that is estimated to fully fund development costs associated with the RewinD-LB Trial. The NIA Grant funds will be disbursed over the course of the trial as costs are incurred and, during the year ended December 31, 2023, we received total cash funding of approximately $6.2 million.

Prior Clinical Studies of Neflamapimod

Phase 2 Clinical Trials Evaluating Neflamapimod in Alzheimer's Disease

Prior to our more recent clinical trials in patients with DLB, two Phase 2a studies of neflamapimod in AD were completed in early 2017. Results from these earlier studies demonstrated that neflamapimod is well tolerated, crosses the blood brain barrier and is pharmacologically active in the brain, including providing us with data around blood-barrier penetration target engagement (biological activity in the brain), and an understanding of dose-response, i.e., the completion of the steps in early clinical studies to successful CNS drug development.

One of these studies, Reverse-SD, was a Phase 2b clinical trial in subjects with AD. 161 subjects were enrolled at 38 sites in the Czech Republic (5 sites), Denmark (3 sites), Netherlands (3 sites), United Kingdom (11 sites) and United States (16 sites) and were randomized 1:1 to receive neflamapimod 40 mg capsules or matching placebo capsules twice daily with food for 24 weeks. Inclusion criteria were as follows: men and women aged 55 to 85 years, with CDR-Global score of 0.5 or 1.0 (i.e., with mild AD); CDR memory sub-score of at least 0.5; MMSE score of 20 to 28, inclusive; positive biomarker for AD, as defined by CSF Aβ1-42 <1000 pg/mL and phospho-tau/Aβ1-42 >0.024 in the Roche Eclesys® immunoassay; receiving either no AD-specific therapy or on a stable dose monotherapy (either cholinesterase inhibitor or memantine; dual therapy excluded).

Including all subjects in the analysis, there was no evident difference between the neflamapimod and placebo groups in the primary clinical efficacy endpoint, the combined change from baseline to week 24 in the z-scores of HVLT of Total Recall and Delayed Recall. However, in the analysis of CSF biomarkers, there were statistically significant effects of neflamapimod treatment, with a reduction relative to placebo, in the change from baseline to week 24 in CSF protein levels of phosphorylated tau (p-tau181, p=0.01 vs. placebo) and total tau (p=0.03 vs. placebo), and a trend on CSF neurogranin (p=0.07 vs. placebo).

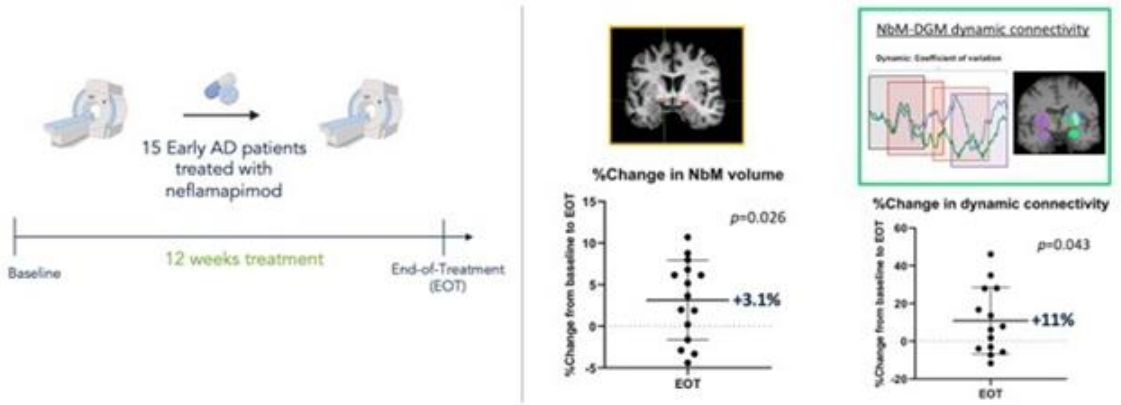
Because in the scientific literature tau pathology has been shown to be downstream (is a consequence) of p38α kinase activity, the effect of neflamapimod on CSF levels of ptau181 and total tau demonstrates target engagement, i.e., these CSF results are consistent with "target engagement" within the brains of subjects. Target engagement is the industry term for the drug having the intended pharmacological effect in humans that would be expected based on its mechanism of action; in this case, that neflamapimod is inhibiting p38α activity. Furthermore, as CSF ptau181 and CSF total tau are considered to reflect neurodegeneration and synaptic dysfunction, respectively, we believe the results also provide objective evidence of neflamapimod impacting the neurodegenerative process in patients, including specifically on synaptic dysfunction.

As a single dose of neflamapimod was utilized in the trial, pre-specified pharmacokinetic pharmacodynamic analyses were conducted to evaluate the results for potential dose-dependency. These analyses showed improvement, relative to the placebo group, in tests of episodic memory in neflamapimod-treated subjects with the highest (top quartile) trough plasma drug concentrations; with positive trends evident both for the primary endpoint (combined change in z-scores of HVLT total recall and delayed recall) and the major secondary endpoint of change in Wechsler Memory Scale Combined Immediate and Delayed Recall composites. This analysis provided critical dose-response information as it indicated that 40mg BID was too low a dose, but that a dose of 40mg TID would achieve therapeutically effective drug concentration levels in the blood.

Results of Imaging of Basal Forebrain by MRI in Patients with Early AD after Treatment with Neflamapimod

With the development and availability of analytic MRI-based techniques to evaluate potential treatment effects on the basal forebrain, the MRI images from patients with mild AD (n=15) from one of our Phase 2a studies were reanalyzed by a specialized neuroimaging group at the Amsterdam Medical Center. The goal of this exploratory analysis, which was presented at the AD/PD meeting in Gothenburg, Sweden in April 2023, was to assess by MRI the treatment effects of neflamapimod on the NbM, the largest cluster of cholinergic neurons in the basal forebrain. Structural and MRI assessments had been conducted as part of the study at baseline and following 12 weeks of treatment with neflamapimod. The additional analysis demonstrated that the NbM volume was statistically significantly higher at EOT (mean 3.1% higher vs. baseline, p=0.026). Eight of 15 subjects had greater than 3% NbM higher volume at EOT, as compared to baseline. Treatment with neflamapimod was also associated with a statistically significantly higher functional dynamic connectivity between the NbM and DGM at EOT (mean 11% higher vs. baseline, p=0.043), with six of 13 subjects showing a greater than 10% higher dynamic NbM-DGM connectivity at EOT, as compared to baseline. We believe the potential reversal of atrophy and recovery of function in neflamapimod-treated subjects in this trial suggests a restoration of cholinergic neurons in the NbM in line with the data generated in previous preclinical studies that demonstrated neflamapimod reversed the neurodegenerative process in the basal forebrain cholinergic system.

Neflamapimod treatment was associated with increased basal forebrain volume and functional connectivity



NbM – Nucleus basalis of Meynert, the largest cluster of cholinergic neurons in the basal forebrain; DGM – Deep Grey Matter
Lin C-P, Noteboom S, Bet M, Alam J, Prins N, Barkhof F, Jonkman L, Schoonheim M, Oral Presentation at AD/PD™ 2023, Gothenburg, Sweden, 1 April 2023

Clinical Safety Results

Adverse events seen in all completed Phase 2 clinical trials evaluating neflamapimod in both CNS and non-CNS disorders are shown in the table below. This includes 149 subjects with either AD or DLB who have received neflamapimod for up to 24 weeks at either 40 mg BID or TID or 125 mg BID. Among this cohort of patients with CNS disorders, the most commonly reported adverse events were headache (15 events, 10%), respiratory infection (11 events, 7%), diarrhea (11 events, 7%), fall, (11 events, 7%), and somnolence (seven events, 5%), all mild to moderate in severity. Headache, diarrhea, and somnolence appear to have the strongest association with neflamapimod treatment.

There were five Serious Adverse Events reported in the 149 subjects with AD and DLB treated with neflamapimod (vs. eight who were administered placebo), involving hypokalemia, myeloma, head injury, brain tumor, and brain lesion, none of which were considered related to neflamapimod.

Adverse Events in Neflamapimod Phase 2 Clinical Trials of ≥ 12 weeks duration in AD or DLB

	Placebo (N=128)	**Neflamapimod (N=140)**
Falls	8 (6%)	11 (8%)
Diarrhea	7 (6%)	10 (7%)
Headache	6 (5%)	9 (6%)
Common Cold/URI	8 (6%)	7 (5%)
Nausea	4 (3%)	6 (4%)
Somnolence	3 (2%)	4 (3%)
Vomiting	4 (4%)	2 (1%)
Fatigue	5 (3%)	1 (1%)

With respect to liver enzyme abnormalities, during 12 weeks of dosing at 250mg BID (i.e., four-fold higher daily dosing than in the recently initiated Phase 2b trial) in 44 subjects with rheumatoid arthritis, elevations in liver transaminase levels were noted in six subjects (14%). Additionally, in one subject (1%) participating in the Reverse-SD 24-week trial in mild AD who received 40 mg BID neflamapimod, ALT and AST levels increased to three times the upper limit of normal. In each instance, subjects were asymptomatic, there were no associated increases in bilirubin, and the elevations resolved with treatment discontinuation.

In the most recently completed AscenD-LB trial involving 91 subjects with DLB, neflamapimod was well tolerated with no treatment discontinuations due to study drug-related adverse events. There were four SAEs reported in the placebo group (haematochezia, internal bleeding, intraparenchymal hemorrhage, asthma exacerbation) and two among the neflamapimod BID treatment group (brain lesions, head injury), all of which were considered unrelated to treatment. In addition, one SAE (brain tumor diagnosis) was reported 34 days after the last dose in a neflamapimod BID recipient. There were no SAEs or early treatment discontinuations in the neflamapimod TID recipients. Liver enzyme abnormalities were not observed in the AscenD-LB trial.

Preclinical Studies

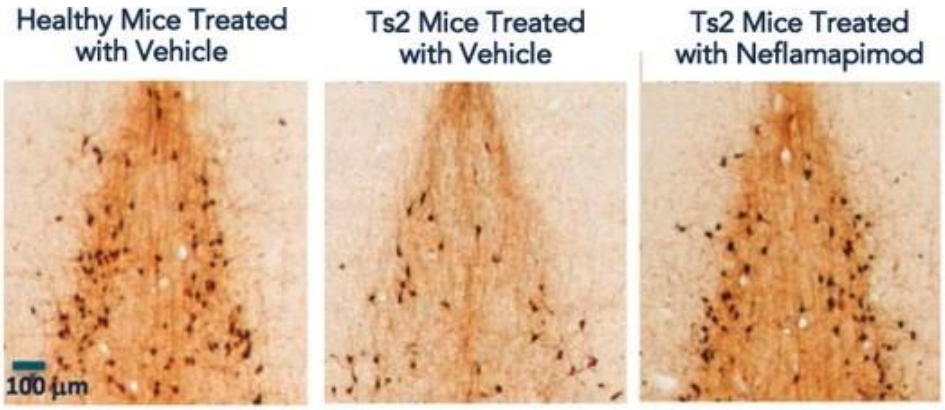
Ts2 Transgenic Mice

Nearly all individuals who have Down Syndrome, characterized by trisomic chromosome 21, develop AD by their fourth decade of life, and have typical AD pathology when autopsied at death. This may be explained by chromosome 21 containing the gene for amyloid-precursor-protein, which is the gene linked to familial or genetic early onset AD in humans. The Ts2 transgenic mouse model of Down Syndrome utilizes mice that are partially trisomic at chromosome 16, which is the mouse equivalent of chromosome 21. Along with developmental behavioral abnormalities, Ts2 mice develop typical early onset dementia pathology, including endosomal abnormalities and cholinergic neurodegeneration in the basal forebrain cholinergic system. Accordingly, Ts2 mice provide an ideal opportunity to evaluate the effects of drug treatment on basal forebrain cholinergic dysfunction and degeneration.

To evaluate the potential of neflamapimod on the neurodegenerative process, the effects of neflamapimod were evaluated in Ts2 mice. Wild-type mice, referred to as either WT or 2N, and Ts2 mice were treated over 28 days, twice daily, with either vehicle or 3 mg/kg of neflamapimod in vehicle, with nine mice in each group. Treatment was initiated at 6-7 months of age, representing a time point at which endosomal pathology and cholinergic neuronal loss is developing. To assess for effects on cholinergic neurodegeneration, ChAT+ neurons were quantitated in the region of the forebrain that is enriched for cholinergic neurons, which is known as the MSN.

At the end of treatment, consistent with current scientific literature, the number of cholinergic neurons in the MSN region was significantly decreased in vehicle-treated TS2 mice compared to vehicle-treated WT mice ($p<0.001$). This effect was reversed with neflamapimod treatment, with the number cholinergic neurons in the MSN increased in neflamapimod-treated TS2 mice compared to vehicle-treated TS2 mice, and the number of ChAT+ neurons were similar to those seen in WT mice ($p<0.001$). Neflamapimod treatment also normalized Rab5 activity and phosphorylated (i.e., activated) p38 MAP kinase and its downstream substrates.

Neflamapimod restores numbers of cholinergic neurons in basal forebrain (i.e., reverses disease progression) in Ts2 transgenic mouse.



Cholinergic neurons, as assessed by staining positive for ChAT+ in the MSN of the basal forebrain, in wild-type treated with vehicle or Ts2 transgenic mice after treatment for four weeks with either vehicle or neflamapimod.

The finding of reversal of disease progression is consistent with studies in the scientific literature that suggest that "loss" of cholinergic neurons in the basal forebrain cholinergic system is not due to cell death. Rather, the "degeneration" and loss of such basal forebrain cholinergic neurons appears to be due to a loss of cholinergic phenotype and functional properties, and neuronal shrinkage, all of which in animal studies can be reversed. That is, the effect of reversing disease progression, evidenced by increased number of cholinergic neurons. This is not a regenerative effect. Rather, we believe it reflects that treatment with neflamapimod is restoring the function of diseased neurons (those that don't express ChAT), allowing them to express ChAT. There is also evidence from studies in early AD, that cholinergic phenotype loss, rather than frank neuronal death and loss, occurs in the basal forebrain of humans as well. We believe this is consistent with the results obtained from the MRI evaluation of neflamapimod-treated AD patients discussed above in whom an increase in the volume of basal forebrain cholinergic neurons was observed in the NbM.

Aged Rat Model

To obtain preclinical proof-of-principle and confirm the role of p38α in the development of synaptic dysfunction, we tested neflamapimod in a rat model of age-related cognitive decline. When evaluated in the Morris-Water-Maze test of spatial learning, rats show cognitive deficits starting at 20 to 22 months of age, which is equivalent to approximately 60 years of age in humans. Of note, because the deficits in Morris-Water-Maze performance can be fully reversed by implanting healthy cholinergic neurons in the basal forebrain, those deficits are believed to be due to basal forebrain cholinergic dysfunction and degeneration.

The results of these tests showed that treatment with neflamapimod fully reversed the learning deficits in the Morris-Water-Maze test in 20- to 22-month-old rats. Specifically, the performance of aged rats on the last day of testing (day 17) showed that animals treated with neflamapimod at the optimal dose performed significantly better than vehicle–treated aged rats ($p=0.007$ for latency; $p=0.01$ for distance). Further, the performance of neflamapimod-treated aged rats was similar to that of young rats (i.e., fully reversed cognitive deficits). The figure below further details the results of these tests, in which two groups of 15 rats each (aged rats with cognitive deficits and a control group of young rats) received vehicle or active drug treatment for 21 days. The Morris-Water-Maze test was conducted on days 4-8 and days 11-17.

Neflamapimod's Potential in Additional Indications

Acute Indication: Recovery after Ischemic Stroke

We believe the therapeutic benefit of targeting neuroinflammation-induced synaptic dysfunction is not limited to chronic neurodegenerative diseases. A drug that improves synaptic function could also be considered for evaluation of the potential to improve brain function after acute neurological injury. In the future, we may investigate neflamapimod in the treatment of certain acute indications such as ischemia-induced stroke. We have generated preclinical evidence suggesting that neflamapimod could improve recovery after ischemic stroke in an animal model.

A treatment to improve recovery from stroke remains a significant unmet medical need. Every year, more than 795,000 people in the United States suffer a stroke, and approximately 610,000 of these are first or new strokes. About 87% of all strokes are ischemic strokes, in which blood flow to the brain is blocked. The prognosis for recovery from stroke is influenced by a number of different factors, including stroke severity, type of stroke, location of infarct, co-morbidity with other disorders, and other clinical complications. The majority of survivors of an acute stroke demonstrate some level of neurological recovery during the three to six months after the initial event. Despite this initial period of recovery, 40 to 50% of patients exhibit persistent neurological deficits.

During the last 10 years, the medical and scientific communities have gained a better understanding of the mechanisms underlying neuronal recovery following a stroke. The major translational opportunity for therapeutics that target recovery after stroke is the time window in which intervention must be initiated. Rather than just the first few hours after the stroke (as is the case with neuroprotection, i.e., acute stroke therapy to reduce the size of stroke), the window for therapeutics that could improve recovery is days and even weeks after an acute stroke. Waiting to initiate therapy until 48 hours after the stroke allows inclusion of a homogenous patient population as the diagnosis and extent of the stroke can be definitively established by that time in most patients (the exception being the minority who have a "stuttering" stroke). As a result, a POC study in stroke recovery is in the range 50-100 patients per treatment arm, compared to 500+ per treatment arm in neuroprotection trials.

The scientific rationale for evaluating neflamapimod to promote recovery after stroke is that the basal forebrain cholinergic system plays a critical role in recovery after ischemic stroke, particularly motor function recovery. The BFC system is suppressed by residual inflammation in the weeks and months after the acute stroke event. Neflamapimod, through the same mechanisms operating in DLB, would be expected to reverse the suppression of BFC function, leading to improved recovery of motor function. Supporting that concept is our preclinical data with neflamapimod demonstrating significant improvement in neurological recovery vs. vehicle treatment, and TUG results from the AscenD-LB clinical trial where positive effects of neflamapimod on basal forebrain mediated control of movement were observed in the clinic.

In a preclinical study of neflamapimod that evaluated effects on recovery after stroke, which has been published in a peer-reviewed scientific journal, transient ischemia of sufficient duration was induced in rats such that significant neurologic disability developed without mortality, and the neurologic disability did not substantially reverse during follow-up without therapy. These rats were then treated with either vehicle or one of two different doses of neflamapimod. The three groups in the study were: vehicle control (n =18), 1.5 mg/kg neflamapimod (n = 21) and 4.5 mg/kg neflamapimod (n = 21). Six weeks of neflamapimod treatment, starting at 48-hours after stroke, led to substantial improvement on multiple parameters of neurologic function compared to vehicle controls ($p<0.001$ for each of global neurologic scores; motor and sensory specific tests).

We have no immediate plans to initiate a clinical trial evaluating neflamapimod as a treatment to improve recovery from acute stroke. However, we have had extensive discussions with stroke experts and have designed a 120-patient, 12-week treatment, placebo-controlled Phase 2 POC trial to improve recovery after ischemic trial in which treatment would be initiated between 3 and 7 days after the acute stroke event that could be initiated to evaluate the effects of neflamapimod, subject to available funding.

Early-Stage Sporadic Alzheimer's Disease

The defining clinical characteristics of early-stage, sporadic AD are deficits in episodic memory (the recollection of everyday events). The driving pathology of sporadic AD is in the hippocampus, the part of the brain in which episodic memory is formed. Accordingly, the amyloid beta therapies have been developed as a treatment for AD based on preclinical data demonstrating that amyloid beta has deleterious effects on synaptic function in the hippocampus. However, scientific literature indicates that degeneration of the basal forebrain cholinergic system also contributes to disease expression and progression in AD, particularly in the early stages, and we believe that a reason for the limited success of amyloid beta directed therapies is that they do not impact disease progression in these basal forebrain cholinergic neurons. In addition to the effects on the BFC system, in experimental studies, p38α expression increased amyloid beta production, while reducing p38α activity decreased amyloid pathology. Further, neflamapimod treatment of transgenic AD mice reduced amyloid beta levels and, in Ts2 mice, neflamapimod reduced the expression of the major enzyme (beta secretase) that produces amyloid beta. Based on these observations, we believe there is a strong rationale for neflamapimod, either as a standalone therapy or in combination with amyloid beta directed therapies.

In addition to the mechanistic and pre-clinical evidence of the potential use of neflamapimod in AD, the AscenD-LB Trial demonstrated clinical outcome results and biomarker results in the CSF and on basal forebrain volume in patients with early AD that we believe suggest neflamapimod's potential use in treating AD.

We have no current plans to initiate a clinical trial evaluating neflamapimod for treatment of early-stage sporadic AD. Rather, assuming success in our ongoing RewinD-LB Trial, we would likely pursue clinical development in early-stage sporadic AD in parallel with our Phase 3 development of neflamapimod in pure DLB, subject to available funding.

Frontotemporal Dementia

FTD is a neurodegenerative disorder characterized by progressive deterioration in behavior, personality, and language abilities, typically affecting individuals between the ages of 40 and 65 including an estimated 50,000 to 60,000 individuals in the U.S. alone. Unlike AD, which primarily targets memory, FTD primarily affects the frontal and temporal lobes of the brain, leading to changes in social conduct, emotional regulation, and decision-making. There are several subtypes of FTD, including the behavioral variant FTD, the most common subtype (approximately half the patients with FTD) and primary progressive aphasia, or PPA, each presenting with distinct symptom profiles. PPA, a subtype of FTD itself, has three main variants: nonfluent/agrammatic variant PPA, semantic variant PPA, and logopenic variant PPA. The prevalence of these PPA subtypes varies, with approximately 40% of PPA patients being nonfluent/agrammatic variant PPA, 40% being semantic variant PPA, and 20% being logopenic variant PPA. As the disease progresses, individuals with FTD may require increasing levels of care and support, with management focusing on alleviating symptoms and maximizing function.

The rationale for potentially evaluating neflamapimod as a treatment for FTD is based on the atrophy of the BFC system also being a driver of disease and the mechanisms that neflamapimod targets (e.g. defects in axonal transport) being operative in FTD. Specifically, when assessed by MRI, the volume of the basal forebrain is reduced, relative to age-matched healthy control, most prominently in patients who semantic variant PPA and behavioral variant FTD and in patients who have "tauopathies" (i.e., patients at autopsy who have tau pathology, rather than TDP-43 pathology). Moreover, in March 2024, at the AD/PD 2024 scientific conference in Lisbon, Portugal, academic collaborators from University College London presented data that showed that p38 MAPK inhibitors generally, and neflamapimod specifically, enhanced axonal transport in a transgenic mouse model of FTD (rg4510 transgenice harboring P301L mutation). Based, in particular, on the transgenic mouse results, we plan to initiate discussions with experts in field and design a phase 2a study to evaluate neflamapimod in the most appropriate subtype of FTD for the mechanism, subject to available funding.

Additional Neflamapimod Development Background

Discovery and Early Development by Vertex

Neflamapimod was originally discovered at Vertex, which initiated clinical investigations in 1999 to determine the effects of the drug on RA. During its clinical investigations of neflamapimod, Vertex completed single and multi-dose Phase 1 studies and initiated Phase 2a development in rheumatoid arthritis. A total of approximately 150 healthy volunteers and patients received neflamapimod in Vertex-sponsored studies for up to one month at 750 mg twice daily and up to 3 months at a dose of 250 mg twice daily.

In a Phase 2a trial in active rheumatoid arthritis conducted by Vertex, a total of 59 healthy volunteers and patients (44 on active drug of 250 mg, and 15 on placebo, twice daily) were enrolled in a 12-week treatment. In this trial, a statistically significant effect of neflamapimod administration on ACR20 response rate was demonstrated ($p = 0.027$ in the primary endpoint analysis: area-under-the-curve of ACR20 response over the 12-week trial period). In a pharmacokinetic/pharmacodynamic analysis, neflamapimod administration also reduced C-reactive protein and IL-6 levels with increasing cumulative drug exposure.

Neflamapimod was generally well tolerated in this RA Phase 2a trial. The most common adverse events associated with neflamapimod were abdominal pain (21% of the 44 healthy volunteers), diarrhea (18%), infection (16%), headache (14%), increased aspartate aminotransferase (14%) and increased alanine aminotransferase (11%). No treatment-emergent neurologic events were seen. Regarding liver function test abnormalities, transaminase levels returned to normal after treatment discontinuation and were not associated with bilirubin elevations. Liver enzyme elevations are a well-known dose-dependent clinical side effect of p38 MAPK inhibitors. In the case of neflamapimod however, we believe the threshold for inducing liver enzyme elevation is a dose level of 250 mg twice daily when administered for more than 4 weeks, which on a daily dose level is four-fold higher than the 40mg TID dose regiment we are moving forward in DLB and other CNS indications (500 mg per day in RA vs. 120 mg per day in DLB and other CNS indications).

Vertex ultimately discontinued its pursuit of neflamapimod in the early 2000s to focus on the clinical development of a therapy for rheumatoid arthritis with a different p38α inhibitor, which, unlike neflamapimod, does not enter the brain. Neflamapimod lay dormant with Vertex until we expressed our interest in exploring the drug for other indications. See “Vertex Agreement” below for additional information.

Toxicology

A full chronic repeated dose toxicology program has been completed in rodents (rats) and non-rodents (dogs). In the rodent species, in the six-month toxicology study, no human relevant findings were evident at dose levels that provided plasma neflamapimod drug concentration levels approximately ten-fold higher than those achieved in the AD clinical trials. In shorter-term studies, the primary target organ was the liver, with findings commencing at plasma drug concentration levels 20-fold higher than the AD clinical trial exposures. In the non-rodent species, in 9- and 12-month toxicology studies, dose dependent findings were evident beginning at plasma neflamapimod drug concentrations more than ten-fold higher than achieved with 40 mg twice daily in AD clinical trials, with minimal to equivocal findings at that dose level in the liver, bone marrow and CNS. The CNS findings demonstrated damage to axons, or nerve fibers, primarily in the spinal cord. p38α and p38β have been reported to have a role in transport of proteins in axons, and therefore we believe these toxicity findings are related to the inhibition of both p38α and p38β at the very high doses administered in the non-rodent studies. The doses we are using in our clinical trials are at least ten-fold lower than the doses at which these effects were observed.

Regulatory Status

We submitted an IND application to the FDA in February 2015. The FDA cleared our application in March 2015, and the IND remains open and active.

The FDA granted neflamapimod Fast Track designation for the treatment of DLB in October 2019.

Following a review of the long-term animal toxicology studies discussed above, the FDA placed a partial clinical hold on our first Phase 2a Trial in mild AD (Study 303) in August 2015, limiting administration of neflamapimod to doses that lead to plasma drug levels which provide at least a 10-fold safety margin to the plasma drug levels in animals that in long-term animal toxicity studies had previously led to minimal or equivocal findings in the liver, bone marrow and CNS. At the present time, this partial clinical hold effectively limits our clinical dosing in the United States to 40 mg of neflamapimod three times daily in patients with a weight of greater than or equal to 50kg (110 pounds), based on agreements with the FDA and on our current understanding of plasma drug levels achieved with neflamapimod in humans. As our current plans across our indications do not envision surpassing this dose level, we do not expect this partial clinical hold to impact our ongoing and planned clinical trials.

In Europe, clinical trial applications in support of our clinical trials have been reviewed and approved by the national regulatory authorities in each of the Netherlands, United Kingdom, Czech Republic and Denmark. In addition, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (the French national regulatory authority) has reviewed and approved a clinical trial application for an investigator-initiated study of neflamapimod in Toulouse, France.

Vertex Agreement

In August 2012, based on our team's previous direct experience with this compound and our understanding of its profile and emerging science around p38α in the brain, we entered into the Vertex Agreement, which granted us an option to acquire an exclusive worldwide license to develop and commercialize neflamapimod for the diagnosis, treatment and prevention of AD and other neurodegenerative diseases. In August 2014, we exercised that option to acquire the license to neflamapimod.

The Vertex Agreement contains certain milestone events and the related payments that we would be obligated to make to Vertex if and when such events occur. Each milestone payment is payable only once for each distinct licensed product, upon the first occurrence of the applicable milestone event. The first expected milestone events concern filing of an NDA, with the FDA for marketing approval of neflamapimod, in the U.S., or a similar filing for a non-U.S. major market, as specified in the Vertex Agreement. The Vertex Agreement also provides that we will make royalty payments to Vertex in the event aggregate net sales, as defined in the agreement, for a commercialized licensed product meet specified thresholds. Such royalties will be on a sliding scale of percentages of net sales in the low- to mid-teens, depending on the amount of net sales in the applicable years. We are also obligated to make a milestone payment to Vertex upon net sales reaching a certain specified amount in any 12-month period. The Vertex Agreement states that royalties will be reduced by 50% during any portion of the royalty term when there is no valid claim of an issued patent within specified patent rights covering the licensed product. We also have the right to deduct, on a country by country basis, from royalties otherwise payable to Vertex under the terms of the Vertex Agreement, 50% of all royalties, upfront fees, milestones and other payments paid by us or any of our affiliates or sublicensees to third parties under licenses that are necessary for the development, manufacture, sale or use of a licensed product, provided that in no event will the royalty payable to Vertex be reduced to less than 50% of the rates specified in the Vertex Agreement, subject to certain adjustments specified therein. In the aggregate, our potential milestone payment obligations, all of which relate to development milestones, under the Vertex Agreement are up to $122.0 million. To date, we have made an aggregate of $100,000 in payments to Vertex. In connection with our obligations under the Vertex Agreement, there is no minimum annual expenditure requirement. Our diligence obligations under the Vertex Agreement have included the making of annual expenditures in connection with the development of neflamapimod, commencement of a Phase 2 clinical trial of neflamapimod, and the commercial sale of neflamapimod within six months of market approval.

The Vertex Agreement provides that we may sublicense the rights granted to us by Vertex, in whole or in part, to a third party (through multiple levels of sublicensing) (i) who is providing services to us in connection with the manufacture or development of the licensed product, solely for the purpose of providing such services, or (ii) with the prior written consent of Vertex, which shall not be unreasonably withheld.

The license term under the Vertex Agreement is deemed to have commenced on August 21, 2014, and continues until the expiration of the royalty term, unless sooner terminated in accordance with the terms of the Vertex Agreement. The royalty term commences on the first commercial sale of a licensed product and ends upon the later of (i) the date of expiration, unenforceability or invalidation of the last valid claim of certain specified underlying patent rights, or (ii) ten years after the date of such first commercial sale. Upon the expiration of the royalty term, the license will convert to a perpetual, fully paid-up non-royalty bearing license with the same scope.

The Vertex Agreement may be terminated by us for any reason upon 90 days' prior written notice to Vertex if such termination occurs before receipt of the first marketing approval of a licensed product, and otherwise upon twelve months' prior written notice to Vertex. Either party may terminate the Vertex Agreement if the other party is in material breach of its obligations thereunder, following a 60-day notice and cure period, or if the other party files for bankruptcy, reorganization, liquidation, receivership, or an assignment of a substantial portion of assets to creditors. The Vertex Agreement also provides that in the event we materially breach any of certain specified diligence obligations as to a specific major market, Vertex's sole remedy for such breach, following the applicable notice and cure period, will be to terminate the license as to such specific major market country.

EIP200 – Novel Co-Crystal of Neflamapimod

We have an issued patent, set to expire in 2038, in the United States for novel co-crystals of neflamapimod with identified, specific, Generally Recognized as Safe compounds that have the potential to improve the solubility and other physical properties of neflamapimod. The development of one of these co-crystals as a product would be supported by composition of matter protection afforded by this patent, providing additional patent protection if we developed such a co-crystal product ourselves, the opportunity to license such a product to another pharmaceutical company while retaining the rights to neflamapimod and other potential benefits. The ability to develop one or more of these co-crystal products requires a fuller evaluation of the potential manufacturing processes than has been performed to date.

Trans Sodium Crocetinate

Prior to the Merger in August 2023, Diffusion focused on developing novel therapies that may enhance the body's ability to deliver oxygen to areas where it is needed most. The most advanced of these product candidates, TSC, has been investigated and developed to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia. Although we have paused all development activity related to TSC, including the initiation of Diffusion's previously announced Phase 2 study of TSC in newly diagnosed GBM patients, we intend to continue to attempt to identify sale or out-licensing transactions for the Company's TSC-related assets.

Sales and Marketing

We do not currently have any infrastructure for the sales, marketing or distribution of an approved drug product. In order to market and successfully commercialize neflamapimod or any other future product candidate, to the extent it or they are approved, we must either develop these capabilities internally or make arrangements with third parties to perform these services. We may also collaborate with strategic partners that have experience in these fields. There are significant expenses and risks involved in establishing our own sales, marketing and distribution functions, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Alternatively, to the extent that we depend on third parties for such services, any revenues we receive will depend upon the efforts of those third parties, and there can be no assurance that such efforts will be successful.

Manufacturing

We do not own or operate manufacturing facilities, nor do we have plans to develop our own manufacturing operations in the foreseeable future. Our lead product candidate, neflamapimod, is a small molecule drug that is manufactured using commercially available technologies.

Our RewinD-LB Trial is being conducted with drug substance (or API) that has already been manufactured. This drug substance was manufactured at an established commercial CMO, that is approved for and manufactures drug both for investigational use and marketed products. We would anticipate utilizing this CMO for clinical trials beyond the Phase 3 clinical trial in DLB, as well as potentially for commercial use if neflamapimod is approved. However, supplies of our neflamapimod drug substance could be interrupted from time to time, and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. For a further description of certain risks related to our manufacturing, see "*Item 1A. Risk Factors – Risks Related to the Company's Clinical Development and Regulatory Approval – The Company's reliance on third parties for the production of neflamapimod may result in delays in the Company's clinical trials or regulatory approvals and may impair the development and ultimate commercialization of neflamapimod, which would adversely impact the Company's business and financial position.*"

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

Competition

Given the potential market opportunity for the treatment of DLB and other neurodegenerative diseases, an increasing number of established pharmaceutical firms and smaller biotechnology/biopharmaceutical companies are pursuing a range of potential therapies for these diseases in various stages of clinical development.

While there are numerous companies pursuing AD disease modifying approaches, we believe there are a limited number of companies and disease modifying approaches for DLB. With regard to public biopharmaceutical companies that we would consider competitive with our approach, and actively evaluating treatments in DLB, we are aware of Eisai Co. Ltd., Cognition Therapeutics, Inc. and Athira Pharma, Inc., all of whom remain in clinical stage development of their potential DLB treatments. None of these companies, however, are developing a treatment specifically targeting patients with pure DLB, the target patient population of our ongoing RewinD-LB Trial.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize, including neflamapimod, may compete with existing therapies and new therapies that may become available in the future.

Our competitors may have significantly greater financial resources, an established presence in the market, and significantly greater expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of neflamapimod, and any other product candidates that we develop to address DLB and other CNS diseases, if approved, are likely to be their efficacy, safety, convenience, price, the level of competition, and the availability of reimbursement from government and other third-party payors. Our potential commercial opportunity could also be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and our product candidates that are important to the development and implementation of our business.

We have made a number of discoveries related to our lead product candidate, neflamapimod, which are reflected in ten main patent families, each of which we wholly own (dates below are without consideration of potential patent term extension, see section titled "—Patent Term Restoration" below):

- The first patent family relates to methods of treating patients suffering from AD, as well as methods of reducing amyloid plaque burden. In this family, we hold issued patents in the United States, Europe, Japan, China, Canada, Australia, and Hong Kong. These patents are set to expire in 2032.

- The second patent family relates to the use of neflamapimod for improving cognition. In this family, we hold issued patents in the United States, Europe, Japan, and a pending application in China. These patents are set to expire in 2035.

- The third patent family relates to co-crystals of neflamapimod in this family, we hold an issued patent in the United States. This patent is set to expire in 2038.

- The fourth patent family relates to methods for promoting recovery of function in patients who have suffered acute neurologic injuries, including those resulting from various forms of stroke. In this family, we hold an issued patent in the United States, Europe, and Japan, and pending applications in Korea and China. These patents are set to expire in 2035-2036.

- The fifth patent family relates to methods of treating patients suffering from dementia. In this family, we have an issued patent the United States for the treatment to patients with MCI to improve episodic memory and a pending application in Europe. Patents that issue in this family, if any, are expected to expire in 2037.

- The sixth patent family relates to formulations of neflamapimod, including pharmaceutical compositions for oral administration exhibiting desirable pharmacokinetics and processes for the manufacture thereof. In this family, we have an issued patent in the United States that is set to expire in 2039.

- The seventh patent family relates to the treatment of DLB. In this family we have pending applications in the United States, Europe, Japan, China, Canada, and Hong Kong. Patents that issue in this family, if any, are expected to expire in 2040.

- The eighth patent family is co-owned by Boston University and relates to methods of treating prion disease. In this family, we have a pending application in the United States. Patents that issue in this family, if any, are expected to expire in 2040.

- The ninth patent family relates to treatment of gait dysfunction related to neurodegenerative disease. An International Application is pending. Patents that issue in this family, if any, are expected to expire in 2041.

- The tenth patent family relates to treatment of a subpopulation of patients having DLB but no substantial Alzheimer's like tau pathology. Patents that issue in this family, if any, are expected to expire in 2042.

Pursuant to the terms and conditions of the Vertex Agreement, Vertex has granted us an exclusive license under specified Vertex patent rights, including U.S patent No. 5,945,418, which relates to the composition of matter for neflamapimod. This patent expired in 2017.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the USPTO delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We also rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements and invention assignment agreements with our collaborators, employees and consultants, as we determine necessary. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses from third parties or cease certain activities.

From time to time, we may find it necessary or prudent to obtain licenses from third party patent owners. Where licenses are available at reasonable cost, such licenses are considered a normal cost of doing business. In other instances, we may use the results of freedom-to-operate studies to guide our early-stage research away from areas where we are likely to encounter obstacles in the form of third-party intellectual property. We strive to identify potential third-party intellectual property issues in the early stages of research in our programs in order to minimize the cost and disruption of resolving such issues.

Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us.

For more information, please see "*Risk Factors—Risks Related to the Company's Intellectual Property*."

Government Regulation

The FDA and comparable regulatory authorities in other countries impose requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These requirements can, in some instances, be substantial and burdensome. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of pharmaceutical products. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development and approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve a pending NDA, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters or other notices of violation, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business and results of operations.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of nonclinical laboratory tests, potentially animal studies and formulation studies in compliance with the FDA's GLP regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an IRB covering each clinical trial site before each trial may be initiated at that site;
- Performance of adequate and well-controlled human clinical trials in accordance with GCP regulations and other clinical trial-related requirements to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA seeking marketing approval;
- A determination by the FDA within 60 days of its receipt of an NDA that the NDA is sufficiently complete to permit a substantial review, in which case the NDA is filed;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Satisfactory completion of FDA audits of clinical trial sites that generated data in support of the NDA to assure compliance with GCP regulations and the integrity of the clinical data and/or FDA audits of the nonclinical studies submitted as part of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of an FDA advisory committee, if one was involved, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and IND

Preclinical, or nonclinical studies generally include laboratory evaluation of product chemistry, toxicity and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for the investigational product's therapeutic use. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA to specify that nonclinical testing for drugs may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations.

An IND sponsor must submit the results of preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans, and it must become effective before human clinical trials may begin. Some long-term nonclinical testing may continue even after the IND is submitted and clinical trials have been initiated. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA issues a notice expressly authorizing the proposed trial to proceed or raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. If the agency imposes a hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators (generally physicians not employed by or under the trial sponsor's control) in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the trial by an IRB for each participating site. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB acting on behalf of each institution participating in the clinical trial must review and approve the trial plan, informed consent forms, and communications to trial subjects before the trial commences at that institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted and must operate in compliance with FDA regulations.

Sponsors of certain clinical trials generally must register such trials and disclose certain trial information within specific timeframes to the NIH for public dissemination on the ClinicalTrials.gov data registry. Information related to the investigational product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion, but such disclosures may be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. Department of Health and Human Services' Final Rule and NIH's complementary policy on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against non-compliant clinical trial sponsors. Competitors may use the publicly available information about clinical trials to gain knowledge regarding the progress of development programs. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1*: The drug candidate is initially administered to healthy human volunteers and tested for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to administer ethically to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.

- *Phase 2*: The drug candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.

- *Phase 3*: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to evaluate the efficacy and safety of the product for its intended use, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product as well as an adequate basis for marketing approval. Typically, two adequate, well-controlled multicenter trials are required by the FDA for drug product approval. Under some limited circumstances, however, the FDA may approve an NDA based upon a single Phase 3 clinical trial plus confirmatory evidence from a post-market trial or, alternatively, a single large, robust, well-controlled multicenter trial without confirmatory evidence.

- *Post-approval Trials:* Sometimes referred to as "Phase 4" clinical trials, these trials may be conducted after initial marketing approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the investigational drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. It is possible that Phase 1, Phase 2 or Phase 3 trials may not be completed successfully within any specified period, or at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require each sponsor of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Concurrent with clinical trials, companies may perform additional nonclinical studies and develop additional information about a drug candidate's chemistry and physical characteristics as well as finalize a process for its manufacturing in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that a drug candidate does not undergo unacceptable deterioration over its proposed labeled shelf life.

Marketing Application Submission, Review by the FDA, and Marketing Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. The NDA must contain proof of the product candidate's safety and substantial evidence of effectiveness for its proposed indication or indications in the form of relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. In particular, a marketing application must demonstrate that the manufacturing methods and quality controls used to produce the drug product are adequate to preserve the drug's identity, strength, quality, and purity. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. FDA approval of an NDA must be obtained before the corresponding drug may be marketed in the United States.

Under PDUFA, each NDA submission is subject to a substantial application user fee, and the sponsor of an approved NDA is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. The application user fee must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

The FDA reviews all NDAs submitted to determine if they are substantially complete before it accepts them for filing and may request additional information rather than accepting a submission for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt and must inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may refuse to file any submission that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the marketing application must be resubmitted with the additional information requested by the agency. The resubmitted application is also subject to review before the FDA accepts it for filing.

Once an NDA is accepted for filing, the FDA's goal is to review the application within 10 months after it accepts the application for filing, or, if the application meets the criteria for "priority review," six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification after the NDA has been accepted for filing. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

During the review process, the FDA reviews the NDA to determine, among other things, whether the product is safe and effective and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued strength, quality, and purity. The FDA may refer any NDA, including applications for novel drug candidates which present difficult questions of safety or efficacy to an advisory committee to provide clinical insight on application review questions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making final decisions on approval.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent manufacture of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies as part of the review process and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Under the PREA, amendments to the FDCA, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires a sponsor that is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early-phase clinical trials or other clinical development programs.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing its products. After the FDA evaluates an NDA and conducts inspections of the manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, information or clarification for FDA to reconsider the application. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the marketing application, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval is limited to the conditions of use (e.g., patient population, indication) described in the application and may entail further limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS to obtain approval for the product. The FDA also may condition approval on, among other things, changes to proposed labeling (e.g., adding contraindications, warnings or precautions) or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. Some types of changes to an approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and separate FDA review and approval. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Fast Track, Priority Review, and Breakthrough Therapy Designations

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept the sections and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. A fast track designated product candidate may also qualify for accelerated approval (described below) or priority review, under which the FDA sets the target date for FDA action on the NDA or biologics license application at six months after the FDA accepts the application for filing.

Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing.

In addition, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all the features of fast track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review and regulatory staff in a proactive, collaborative, cross-disciplinary review, where appropriate. A drug designated as breakthrough therapy is also eligible for accelerated approval if the relevant criteria are met.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast track, priority review and breakthrough therapy designations do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or approval process.

Accelerated Approval

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when it has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product candidate's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the product. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs or biologics previously granted accelerated approval. Under the act's amendments to the FDCA, FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of the NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a written request does not require the sponsor to undertake the described studies.

Abbreviated NDAs for Generic Drugs

In 1984, with passage of the Hatch-Waxman Act, which established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. To obtain approval of a generic drug, an applicant must submit an ANDA to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Clinicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing an NCE. For the purposes of this provision, an NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (described below), in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for an NDA, 505(b)(2) NDA or supplement thereto if one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. The three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed by the original applicant;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the follow-on application in question has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. The manufacturer and its products are also subject to similar post-approval requirements by regulatory authorities comparable to FDA in jurisdictions outside of the United States where the products are approved. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or a supplement to an NDA, which may require the applicant to develop additional data or conduct additional nonclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet applicable cGMP requirements to the FDA's or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic prescheduled or unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturing organizations that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including voluntary recall and regulatory sanctions as described below.

Once an approval or clearance of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or other enforcement-related letters, or clinical holds on post-approval clinical trials;
- Refusal of the FDA to approve pending marketing applications or supplements to approved marketing authorizations, or suspension or revocation of product approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Injunctions or the imposition of civil or criminal penalties;
- Consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and/or
- Mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the DSCSA was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period, which culminated in November 2023. Most recently, the FDA announced a one-year stabilization period to November 2024, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes, if any, may be.

Other U.S. Health Care Laws and Regulations

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare and Medicaid. These laws include:

- The federal AKS prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute;
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the CMS information related to payments and other transfers of value to physicians, certain advanced non-physician health care practitioners, and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, such physicians, non-physician health care practitioners, and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by nongovernmental third-party payors, including private insurers.

The majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Due to the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

Pharmaceutical Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of our products, when and if approved for marketing in the United States, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. In addition, these third-party payors are increasingly reducing reimbursements for medical products, drugs and services. Furthermore, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Limited third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, the primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. In recent years, the U.S. Congress has considered reductions in Medicare reimbursement levels for medicines and biologics administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for most drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products we may market in the future. While Medicare regulations apply only to pharmaceutical benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In recent years, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Notably, the CREATES Act, which became effective on December 20, 2019, addresses concerns articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

More recently, in August 2022, President Biden signed into the law the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single-source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

In addition to the IRA's drug price negotiation provisions, President Biden's Executive Order 14087, issued in October 2022, called for the CMS innovation center to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs. In February 2023, CMS published its report which described three potential models focusing on affordability, accessibility and feasibility of implementation for further testing by the CMS Innovation Center. As of February 2024, the CMS Innovation Center continues to test the proposed models and has started to roll out plans for access model testing of certain product types (e.g., cell and gene therapies) by states and manufacturers.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical developers like us. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Regulation Outside the United States

For countries outside of the United States, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, clinical trials must be conducted in accordance with GCP and the other applicable regulatory requirements. To the extent that any of our product candidates, once approved, are sold in a foreign country, we and our collaborators will be subject to applicable foreign laws and regulations, which may include, for instance, post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals. If we or our collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

For example, to market our future products in the EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining an MA. There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, is based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, including medicines containing novel active substances to treat neurodegenerative disorders. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA (other than those intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, or viral diseases, which must be authorized through the Centralized Procedure), or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the procedures described above, before granting the MA the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

In April 2023 the European Commission issued a proposal that will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the European Union.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the nonclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic applicant from commercializing its product in the European Union until 10 years have elapsed from the initial authorization of the reference product in the European Union. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Our People

Overview

As of December 31, 2023, we had eight employees, all of whom we classify as full-time employees, up from four employees as of December 31, 2022. We consider the relationship with our employees to be good. We also engage outside consultants and contractors with unique expertise and skills for specific purposes.

Our success depends upon our ability to attract and retain highly qualified management and technical employees. Talent management is critical to our ability to execute our long-term growth strategy, including providing career growth, on-the-job learning opportunities and competitive compensation. We are committed to an inclusive culture which values equality, opportunity and respect. We are focused on the engagement and empowerment of our employees through the demonstration of these foundational values.

None of our employees are represented by labor unions or covered by collective bargaining agreements.

Company Culture; Diversity and Inclusion

We believe that an inclusive culture is required to understand and develop products that benefit all patients. By embracing differences, we aim to foster an environment of respect and trust in an effort to facilitate creativity, spark passion and help us achieve better outcomes for all those who work at and with CervoMed. We are committed to creating and maintaining a workplace free from discrimination or harassment, including on the basis of any class protected by applicable law, and our recruitment, hiring, development, training, compensation, and advancement practices are based on qualifications, performance, skills, and experience without regard to gender, race, ethnicity or other demographics.

Our management team and employees are expected to exhibit and promote honest, ethical, and respectful conduct in the workplace, including adhering to the standards for appropriate behavior set forth in our code of conduct. An “open door” policy is maintained at all levels of the organization and any form of retaliation against an employee reporting or registering complaints in the event of any violation of our policies is strictly prohibited.

Compensation and Benefits

We operate in a highly competitive environment for human capital, particularly as we seek to attract and retain talent with relevant experience in the biotechnology and pharmaceutical sectors. Therefore, we strive to provide a total rewards package to our employees that is competitive with our peer companies and helps meet the needs of our employees. This package currently includes competitive salaries, a cash bonus plan, a comprehensive healthcare benefits package (including a 90% employer contribution to family medical coverage), unlimited paid time off, a company-sponsored 401(k) savings plan, short-term and long-term disability, and other benefits, as well as remote working and flexible work schedules. We also offer every full-time employee the benefit of equity ownership in CervoMed through stock option grants with vesting conditions designed to facilitate retention through the opportunity to benefit financially from our growth and profitability, as they generally vest over a three- or four-year period. We believe these grants also help promote alignment between our employees and our stockholders.

Employee Engagement, Safety and Wellness

At CervoMed, we believe that health matters to everyone and that the success of our business is fundamentally connected to the physical and mental well-being of our people. Accordingly, the safety health, and wellness of our employees is one of our top priorities. We are committed to developing and fostering a work environment that is safe, professional, and promotes teamwork, diversity, and trust in order to afford all of our employees the opportunity to contribute to the best of their abilities. In addition to the benefits package described above, in recent years, we have taken certain measures and responded to changes in our operational needs, including actions designed to further promote a safe work environment for our employees, such as investing in technology solutions to support increased work-from-home capabilities and moving to an unlimited paid leave policy.

Development and Training

Our employees are encouraged to attend scientific, clinical, technological, and other relevant meetings and conferences and we strive to provide employees access to a broad set of internal resources intended to help them be successful, including a variety of training and educational materials. We have also implemented a comprehensive employee evaluation program tied to the achievement of individual, team, and company goals to help further support, retain, and develop our people and further promote alignment of interests between our employees and our stockholders.

Corporate Information

Our History

We were originally incorporated under the laws of the State of Nevada on January 10, 1995 and reincorporated under the laws of the State of Delaware on June 18, 2015. On August 16, 2023, we completed the merger of Merger Sub with and into EIP, which was treated as a "reverse recapitalization" under U.S. GAAP pursuant to which EIP's historical results of operations replaced the Company's for all periods prior to the merger. Immediately following the closing of the merger, we changed our name from "Diffusion Pharmaceuticals Inc." to "CervoMed Inc."

Where to Find Us

Our principal corporate office is located at 20 Park Plaza, Suite 424, Boston, Massachusetts 02116, and our telephone number is (617) 744-4400. Our website, www.cervomed.com, including the Investor Relations section, ir.cervomed.com, contains a significant amount of information about the Company.

However, the information included on our website is not incorporated by reference into, and should not be considered part of, this prospectus or any other filings we make with the SEC.

Other Available Information

We make available on or through our website certain reports that we file with or furnish to the SEC in accordance with Exchange Act. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K, as well as any amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. The SEC also maintains a website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding the Company and other issuers that file electronically with the SEC. We also make available, free of charge and through our website, the charters of the committees of the Board, our Corporate Governance Guidelines, and our Code of Business Conduct and Ethics.

MANAGEMENT

The following table sets forth certain information about our directors and executive officers as of April 29, 2024.

Name	Age	Position/Title
Executive Officers:		
John Alam, M.D.	62	Chief Executive Officer, President and Director
Kelly Blackburn	60	Senior Vice President, Clinical Development
Robert J. Cobuzzi, Jr., Ph.D.	59	Chief Operating Officer and Director
William Elder	41	General Counsel and Corporate Secretary
William Tanner, Ph.D.	65	Chief Financial Officer
Non-Employee Directors:		
Joshua Boger, Ph.D.	73	Chair of the Board
Sylvie Grégoire, PharmD	62	Director
Jane H. Hollingsworth	66	Director
Jeff Poulton	56	Director
Marwan Sabbagh, M.D.	58	Director
Frank Zavrl	58	Director

Executive Officers

John Alam, M.D., has served as our President and Chief Executive Officer and as a director since August 2023. Dr. Alam was EIP's co-founder and served as EIP's President and Chief Executive Officer and as a member of EIP's board of directors from April 2018 to August 2023. Prior to that, Dr. Alam served as a managing member of EIP Pharma, LLC, EIP's predecessor entity, from its inception in 2010. From January 2011 to August 2014, Dr. Alam served as therapeutic area head for diseases of aging at Sanofi S.A. (NASDAQ: SNY), a global pharmaceutical company. From 1997 until 2008, he held positions of increasing responsibility at Vertex (NASDAQ: VRTX), most recently as Chief Medical Officer and Executive Vice President, Medicines Development. From 1991 to 1997, Dr. Alam worked at Biogen Inc. (NASDAQ: BIIB), where he led the clinical development of Avonex, a drug that treats multiple sclerosis. From 2014 to 2022, Dr. Alam served as a member of the board of directors of the Alliance for Aging Research, a non-profit organization dedicated to promoting innovation to address the healthcare needs of older Americans. Dr. Alam received an S.B. in chemical engineering from the Massachusetts Institute of Technology and a M.D. from Northwestern University School of Medicine. Dr. Alam completed an internal medicine residency at Brigham and Women's Hospital and a post-doctoral fellowship at Dana-Farber Cancer Institute.

We believe that Dr. Alam is qualified to serve as a director due to his service as the Company's and EIP's president and chief executive officer and his extensive knowledge of our Company and significant background in pharmaceutical research and development.

Kelly Blackburn, M.H.A., has served as Senior Vice President, Clinical Development of the Company since August 2023. Ms. Blackburn previously served as Senior Vice President, Clinical Development of EIP from May 2018 to August 2023. Previously, Ms. Blackburn served as Vice President, Clinical Affairs of aTyr Pharma, Inc. (NASDAQ: LIFE) from July 2013 to July 2016. Ms. Blackburn served as a clinical development consultant from September 2012 to July 2013 to a number of companies, including Agios Pharmaceuticals, Promedior Inc. and aTyr Pharma. Prior to this, Ms. Blackburn was the Vice President, Clinical Development Operations at Vertex (NASDAQ: VRTX), a global biotechnology company, from September 2006 to September 2012 overseeing programs for Incivek and Kalydeco, as well as their early development programs. From September 2002 to August 2006, Ms. Blackburn was Director of Clinical and Safety Operations for Millennium Pharmaceuticals where she was responsible for the VELCADE program which was successfully approved during her tenure. Ms. Blackburn holds a B.S. in biochemistry from University of New Hampshire, an M.H.A. from Quinnipiac College and a M.Ed. from Cambridge College.

Robert J. Cobuzzi, Jr., Ph.D., has served as our Chief Operating Officer since August 2023 and as a director since November 2023. Dr. Cobuzzi previously served as Diffusion's President and Chief Executive Officer from September 2020 to August 2023, and was a member of Diffusion's board of directors from January 2020 until August 2023. Dr. Cobuzzi also currently serves as a Venture Partner and Chairman of the Business Development Board for Sunstone Life Science Ventures, an independent European venture capital investment firm focused on life science therapeutic innovations. Previously, Dr. Cobuzzi served as an Advisor to the Mitochondrial Disease Research Program at the Children's Hospital of Philadelphia, an internationally recognized hospital and research center devoted to children, from January 2019 to April 2020, and as President and Chief Executive Officer of MitoCUREia, Inc., an affiliated company, from July 2019 to July 2020. From 2005 to 2018, Dr. Cobuzzi served in various roles at Endo International PLC, a specialty branded and generic pharmaceuticals manufacturer, most recently serving as President of Endo Ventures Limited. Dr. Cobuzzi received his Bachelor of Arts in Biochemistry and Art History from Colby College and his Ph.D. in Molecular and Cellular Biochemistry from Loyola University Chicago. He served as a Post-doctoral Fellow in Experimental Therapeutics at Roswell Park Cancer Institute.

We believe Dr. Cobuzzi is qualified to serve on the board of directors due to his experience and insight with drug development and business development and funding, both in the U.S. and abroad, as well as his experience and background as an executive and director.

William Elder has served as the Company's General Counsel & Corporate Secretary since September 2020 and currently serves as the Company's Acting Principal Financial Officer, a position he has held since March 2024. Mr. Elder also previously served as Diffusion's Principal Financial Officer from June 2023 to August 2023 and as a part-time consultant to Diffusion from July 2020 to September 2020. Prior to joining Diffusion, Mr. Elder principally served as president and chief executive officer of BillyVonElds, LLC, a season-long and daily fantasy sports company, where he managed all corporate, legal, and operational aspects of the business from April 2019 to September 2020. From 2011 to February 2019, Mr. Elder served as a corporate and securities associate for Dechert LLP, an international law firm, where Mr. Elder's practice focused primarily on counseling public companies on securities laws and regulatory requirements, corporate governance matters, and financial transactions in the equity and debt markets. He received his J.D. from the University of Pennsylvania Law School, an M.S. in finance from Villanova University, and a B.A. in economics from Tufts University.

William Tanner, Ph.D., has served as the Company's Chief Financial Officer since August 2023. He previously served as EIP's Chief Financial Officer from September 2022 to August 2023. Dr. Tanner has been a consultant at Danforth Advisors, a financial and operational company for outsourced corporate and clinical business functions, since November 2021 and previously served as the chief financial officer of Danforth Advisors from November 2021 to April 2022. He co-founded ImmunoGenesis, Inc., an immuno-oncology company, in May 2019 and served as its Chief Financial Officer until October 2021. From November 2022 to April 2023, Dr. Tanner served as the chief financial officer of siRNAgen Therapeutics and from May 2021 to April 2023, he served as the interim chief financial officer of Synthis Therapeutics, Inc. Prior to that, Dr. Tanner was a managing director at Brookline Capital Markets from April 2019 to May 2019, an analyst at Cantor Fitzgerald & Co. from November 2016 to November 2018, and an analyst at Guggenheim Securities from May 2015 to November 2016. Dr. Tanner earned his B.S. and Ph.D. in physiology from Texas A&M University and completed post-doctoral training in Washington University School of Medicine's Department of Cell Biology and in the Center for Immunology. He received his MBA from Washington University's Olin Business School.

Non-Employee Directors

Joshua S. Boger, Ph.D., has served as a director and the Chair of the Board since February 2024. Dr. Boger is the founder of Vertex (NASDAQ: VRTX) and served as its Chief Executive Officer from 1992 to May 2009, as chairman of its board of directors from 1997 to 2006, and as a director from 1989 until his retirement from the Vertex board of directors in 2017. Prior to founding Vertex in 1989, Dr. Boger held the position of Senior Director of Basic Chemistry at Merck Sharp & Dohme Research Laboratories in Rahway, New Jersey, where he headed both the Department of Medicinal Chemistry of Immunology & Inflammation and the Department of Biophysical Chemistry. Dr. Boger currently serves as executive chairman of the board of directors of Alkeus Pharmaceuticals, Inc., a privately-held biotechnology company focused on treating degenerative eye diseases. Dr. Boger holds a B.A. in chemistry and philosophy from Wesleyan University and M.S. and Ph.D. degrees in chemistry from Harvard University. His postdoctoral research in molecular recognition was performed in the laboratories of the Nobel-prize winning chemist, Jean-Marie Lehn in Strasbourg, France. He is the author of over 50 scientific publications and holds 32 issued U.S. patents in pharmaceutical discovery and development.

We believe Dr. Boger is qualified to serve on the board of directors due to his management experience in the pharmaceutical and biotechnology sector and his extensive knowledge of our Company and significant background in pharmaceutical research and development.

Sylvie Grégoire, Pharm.D., has served as a director since August 2023 and previously served as Chair of the Board from August 2023 to February 2024. Dr. Grégoire was EIP's co-founder and served as EIP's Executive Chair and as a member of EIP's board of directors from April 2018 to August 2023. From May 2013 to May 2019, Dr. Grégoire served as a director for Vifor Pharma AG (SIX: VIFN), a global pharmaceutical company focused on treatments for renal disease. From September 2007 to May 2013, Dr. Grégoire served as President of the Human Genetic Therapies division of Shire plc, a global biopharmaceutical company acquired by Takeda Pharmaceutical Company Limited. From 2005 to 2008, she served as a director of IDM Pharma, Inc., a publicly traded biotechnology company that now operates as a subsidiary of Takeda Pharmaceuticals Company Limited, including serving as its Executive Chair from August 2006 to October 2007. From 2004 to 2005, Dr. Grégoire served as President, Chief Executive Officer and Executive Member of the board of directors of GlycoFi, Inc., a private biotechnology company now part of Merck and Co., Inc. Prior to that, Dr. Grégoire held various leadership positions at Biogen, Inc. (NASDAQ: BIIB), including Vice-President (head) of Regulatory Affairs, Vice-President (head) of Manufacturing, and as Executive Vice President of Technical Operations. Dr. Grégoire also served at Merck and Co., Inc. in the US and internationally in clinical research and regulatory affairs. Dr. Grégoire serves on the board of directors of Novo Nordisk A/S (NYSE: NVO), a global pharmaceutical company, where she sits on the audit committee, the nomination committee and the research and development committee. Dr. Grégoire has also served on the board of directors of Revvity Inc (NASDAQ: RVTY) (previously PerkinElmer, Inc. (NYSE: PKI)), a publicly traded company and a provider of products, services and solutions for the diagnostics, life sciences and applied markets, since February 2015. At Revvity, she also serves on the compensation and benefits committee and the nominating and corporate governance committee. In addition, Dr. Grégoire served as chair of the board of directors of Corvidia Therapeutics, Inc., from 2016 to 2020, a private company focused on treatments for cardio-renal diseases. Corvidia was sold to NovoNordisk in 2020. Dr Grégoire has also served on the board of F2G Ltd, a privately held company developing treatments for severe rare mold infections since December 2021 where she is also the chair of the Commercial Committee. Dr. Grégoire received a bachelor's degree in Pharmacy from Laval University and a doctoral degree in Pharmacy from the State University of New York at Buffalo.

We believe that Dr. Grégoire is qualified to serve on our board of directors due to her management experience in the pharmaceutical and biotechnology sector and her broad experience of service on other boards of directors.

Jane H. Hollingsworth, J.D., has served as a director since September 2020. Ms. Hollingsworth previously served on Diffusion's board of directors from September 2020 to August 2023, including as Chair of the board from August 2021 to August 2023. She currently serves as the founding Managing Partner of Militia Hill Ventures, an organization that creates, builds, and invests in life sciences companies, a role she has held since 2013. While at Militia Hill, Jane co-founded and currently serves as Executive Chair of Eliksa Therapeutics, a regenerative medicine company, co-founded and served as Executive Chair of Spirovant Sciences, a gene therapy company sold to Sumitomo Dainippon Pharma, and served as Executive Chair and CEO of Immunome Inc. (NASDAQ: IMNM), a cancer immunotherapy company. Prior to founding Militia Hill, Ms. Hollingsworth co-founded and served as Chief Executive Officer of NuPathe, Inc., a neuroscience focused biopharmaceutical company. She also co-founded and served as EVP of Auxilium Pharmaceuticals, a urology and rare disease focused biopharmaceutical company. Ms. Hollingsworth also currently serves on the boards of the life science companies Afimmune Ltd. and Ribonova, and various industry and community organizations, including the University City Science Center, the Kimmel Center for the Performing Arts and Breatcancer.Org. Ms. Hollingsworth received her B.A. from Gettysburg College and her J.D. from Villanova University.

We believe that Ms. Hollingsworth is qualified to serve on our board of directors due to her industry perspective and experience, including as chief executive officer and director of a publicly-traded biopharmaceutical company, as well as her depth of her other operating and senior management experience in the industry and educational background.

Jeff Poulton has served as a director since August 2023. Mr. Poulton previously served on EIP's board of directors from April 2018 to August 2023. Since July 2019, Mr. Poulton has served as Chief Financial Officer at Alnylam Pharmaceuticals, Inc. (NASDAQ: ALNY), a global biopharmaceutical company based in Cambridge, Massachusetts. From January 2018 to April 2019, Mr. Poulton served as chief financial officer at Indigo Agriculture, a plant microbiome company. From September 1998 to December 2017, Mr. Poulton held various roles of increasing responsibility at Shire plc, a biotechnology company, culminating in his service as chief financial officer from July 2014 to December 2017 and a member of Shire's executive committee and board of directors from January 2015 to December 2017. During his tenure at Shire, Mr. Poulton also lead Shire's rare disease US/APAC and LATAM commercial operations, as well as Shire's rare disease business unit. Prior to his tenure at Shire, Mr. Poulton led corporate finance and business development initiatives in both the gas and electric utilities industry and the materials manufacturing sector, serving in financial leadership positions at Cinergy Corporation and PPG Industries, Inc. Mr. Poulton also served as a U.S. Navy Commissioned Officer aboard the USS Peoria. Mr. Poulton holds a B.A. in Economics from Duke University and an M.B.A. in Finance from the Kelly School of Business at Indiana University.

We believe that Mr. Poulton is qualified to serve on our board of directors due to his significant financial and operational experience in the life sciences industry.

Marwan Sabbagh, M.D., has served as a director since August 2023. Dr. Sabbagh previously served as a member of EIP's board of directors from November 2021 to August 2023. Since October 2021, Dr. Sabbagh has served as a professor in the Department of Neurology, and recently became Vice Chairman for Research, at the Barrow Neurological Institute. Dr. Sabbagh is board certified in neurology by the American Board of Psychiatry and Neurology and is a fellow of the American Academy of Neurology. Previously, from May 2018 to October 2021, Dr. Sabbagh was a neurologist and director at the Cleveland Clinic Lou Ruvo Center for Brain Health. Prior to his time at the Cleveland Clinic, Dr. Sabbagh was a director and neurologist at the Banner Sun Health Research Institute from 2000 to 2015. Dr. Sabbagh served on the board of directors of Quince Therapeutics, Inc. (f/k/a/ Cortexyme, Inc.) (NASDAQ: QNCX) from March 2022 to September 2022. Dr. Sabbagh earned his medical degree from the University of Arizona College of Medicine and his undergraduate degree from the University of California Berkeley. He completed his neurology residency at Baylor College of Medicine and a geriatric neurology and dementia fellowship at the University of California San Diego School of Medicine.

We believe that Dr. Sabbagh is qualified to serve on our board of directors due to his expertise in neurological diseases and extensive clinical development experience.

Frank Zavrl has served as a director since August 2023. Mr. Zavrl previously served as a member of EIP's board of directors from April 2018 to August 2023. From September 2017 to March 2018, Mr. Zavrl served as a member of the board of directors of EIP Pharma, LLC. Prior to that, Mr. Zavrl served on the board of directors of Puma Biotechnology, Inc. (NASDAQ: PBYI), a publicly-traded company focused on the treatment of cancer, from September 2015 to July 2020. From 2002 to 2011, Mr. Zavrl served as a Partner at Adage Capital Management, L.P., an asset management company, where Mr. Zavrl specialized in biotechnology investments. From 1999 to 2002, Mr. Zavrl served as a Portfolio Manager at Merlin BioMed Group, a healthcare investment firm. Prior to that, Mr. Zavrl served from 1998 to 1999 as an analyst at Scudder Kemper Investments Inc., focusing on biotechnology investments. Mr. Zavrl received a B.S. in Biochemistry from the University of California, Berkeley and an M.B.A. from the Tuck School of Business at Dartmouth College.

We believe that Mr. Zavrl is qualified to serve on our board of directors due to his significant investment experience in pharmaceutical and biotechnology companies.

Family Relationships

John Alam, M.D., and Sylvie Grégoire, Pharm.D. are husband and wife and therefore "immediate family members" as defined in Item 404 of Regulation S-K. Other than their relationship, there are no family relationships among any of our directors or executive officers.

Number of Directors

Our Bylaws provide that the Board will consist of at least one member, or such other number as may be determined by the Board or our stockholders. The Board has currently fixed the number of directors at eight.

Additional Information About Current Directors

We believe that all of our directors and director nominees display personal and professional integrity; satisfactory levels of education and/or business experience; broad-based business acumen; an appropriate level of understanding of our business and its industry and other industries relevant to our business; the ability and willingness to devote adequate time to the work of the Board and its committees; a fit of skills and personality with those of our other directors that helps build a board of directors that is effective, collegial and responsive to the needs of our Company; strategic thinking and a willingness to share ideas; a diversity of experiences, expertise and background; and the ability to represent the interests of all of our stockholders. The information presented above regarding each director and nominee for director also sets forth specific experience, qualifications, attributes and skills that, among other things, led the Board to the conclusion that he or she should serve as a director in light of our business and structure.

There are no arrangements or understandings with another person under which the Company's directors and executive officers were or are to be selected as a director or executive officer. Additionally, no director or executive officer of the Company is involved in legal proceedings which require disclosure under Item 401 of Regulation S-K.

Directors & Director Independence

Nasdaq rules generally require that independent directors must comprise a majority of the listed company's board of directors. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, the Board has determined that five of our eight current directors — Joshua S. Boger, Ph.D., Jane H. Hollingsworth, J.D., Jeff Poulton, Marwan Sabbagh, M.D., and Frank Zavrl — are "independent directors" as that term is defined under the applicable rules and regulations of the SEC and under the Listing Rules of the Nasdaq Capital Market.

Diversity Matrix

The following Board Diversity Matrix presents our Board's diversity statistics in accordance with Nasdaq Rule 5606, as self-disclosed by our directors.

Board Diversity Matrix (As of April 29, 2024)				
Total Number of Directors 8				
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Gender:				
Directors	2	6		
Number of Directors Who Identify in Any of the Categories Below:				
African American or Black				
Alaskan Native or Native American				
Asian (including South Asian)		1		
Hispanic or Latinx				
Native Hawaiian or Pacific Islander				
White	2	5		
Two or More Races or Ethnicities				
LGBTQ+				
Persons with Disabilities				

Board Leadership Structure

The Board believes that our stockholders are best served if the Board retains the flexibility to adapt its leadership structure to applicable facts and circumstances, which necessarily change over time. Accordingly, under our Corporate Governance Guidelines, the office of Chair of the Board and Chief Executive Officer may or may not be held by one person. The Board believes it is best not to have a fixed policy on this issue and that it should be free to make this determination based on what it believes is best under the circumstances.

Currently, Joshua S. Boger, Ph.D., serves the Chair of the Board and John Alam, M.D. serves as our President and Chief Executive Officer; Dr. Grégoire served as Chair of the Board until Dr. Boger's appointment to the Board and as Chair, effective February 7, 2024. The Board believes that it is currently in the best interests of the Company's stockholders to separate these offices. This separation allows for our Board Chair to act as a bridge between the Board and the operating organization, while our President and Chief Executive Officer focuses on running the Company's business. The Board believes that this separation allows for a more effective utilization of the proven leadership capabilities, breadth of industry experience and business success of the individuals holding both positions, and that the Company and its stockholders are best currently served by this leadership structure.

Executive Sessions

Generally, at regular meetings of the Board, our independent directors meet in executive session with no company management present during a portion of the meeting.

Board Committees

The Board has three standing committees: the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee. Each of these committees has the composition and responsibilities described below. The Board, from time to time, may establish other committees to facilitate the management of the Company or oversight of certain affairs, and may change the composition and the responsibilities of the existing committees. Each of the three standing committees has a charter which can be found on the Investor Relations—Corporate Governance section of our corporate website at www.cervomed.com.

Audit Committee

Responsibilities. The primary responsibilities of the Audit Committee include:

- overseeing our accounting and financial reporting processes, systems of internal control over financial reporting and disclosure controls and procedures on behalf of the Board and reporting the results or findings of its oversight activities to the Board;
- having sole authority to appoint, retain and oversee the work of our independent registered public accounting firm and establishing the compensation to be paid to the independent registered public accounting firm;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and/or auditing matters and for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and pre-approving all audit services and permissible non-audit services to be performed for us by our independent registered public accounting firm as provided under the federal securities laws and rules and regulations of the SEC;
- overseeing our system to monitor and manage risk, and legal and ethical compliance programs, including the establishment and administration (including the grant of any waiver from) a written code of ethics applicable to each of our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions; and
- oversight of cybersecurity risks.

The Audit Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition and Audit Committee Financial Expert. The current members of the Audit Committee are Ms. Hollingsworth, Mr. Poulton, and Mr. Zavrl. Mr. Poulton is the chair of the Audit Committee. From January 1, 2023, until the completion of the Merger, Ms. Hollingsworth, Mark T. Giles and Alan Levin were the members of Diffusion's Audit Committee, with Mr. Levin serving as chair.

Each current member of the Audit Committee qualifies as "independent" for purposes of membership on audit committees under the Listing Rules of the Nasdaq Capital Market and the rules and regulations of the SEC and is "financially literate" under the Listing Rules of the Nasdaq Capital Market. In addition, the Board has determined that Mr. Poulton qualifies as an "audit committee financial expert" as defined by the rules and regulations of the SEC and meets the qualifications of "financial sophistication" under the Listing Rules of the Nasdaq Capital Market as a result of his experience in senior financial positions. Stockholders should understand that these designations related to the Audit Committee members' experience and understanding with respect to certain accounting and auditing matters are disclosure requirements of the SEC and the Nasdaq Capital Market and do not impose upon any of them any duties, obligations or liabilities that are greater than those generally imposed on a member of the Audit Committee or of the Board.

Processes and Procedures for Complaints. The Audit Committee has established procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, or auditing matters, and the submission by our employees, on a confidential and anonymous basis, of concerns regarding questionable accounting or auditing matters. Our personnel with such concerns are encouraged to discuss their concerns with their supervisor first, who in turn will be responsible for informing our President and Chief Executive Officer of any concerns raised. If an employee prefers not to discuss a particular matter with his or her own supervisor, the employee may instead discuss such matter with our President and Chief Executive Officer. If an individual prefers not to discuss a matter with the President and Chief Executive Officer or if the President and Chief Executive Officer is unavailable and the matter is urgent, the individual is encouraged to contact the Chair of the Audit Committee, Mr. Poulton.

A copy of the Audit Committee's written charter is publicly available on our website at www.cervomed.com.

Compensation Committee

Responsibilities. The primary responsibilities of the Compensation Committee include:

- determining the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to our Chief Executive Officer and other executive officers;
- determining any revisions to corporate goals and objectives with respect to compensation for our Chief Executive Officer and other executive officers and establishing and leading a process for the full Board to evaluate the performance of our Chief Executive Officer and other executive officers in light of those goals and objectives;
- administering our equity-based compensation plans, including determining specific grants of options and other awards for executive officers and other employees under our equity-based compensation plans; and
- establishing and leading a process for determination of the compensation applicable to the non-employee directors on the Board.

The Compensation Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition. The current members of the Compensation Committee are Ms. Hollingsworth, Mr. Poulton, and Mr. Zavrl. Mr. Zavrl is the chair of the Compensation Committee. Each of the three current members of the Compensation Committee is an "independent director" under the Listing Rules of the Nasdaq Capital Market and a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act. From January 1, 2023, until the completion of the Merger, Ms. Hollingsworth, Diana Lanchoney, M.D., and Robert Adams were the members of Diffusion's Compensation Committee, with Mr. Adams serving as chair.

Processes and Procedures for Consideration and Determination of Executive Compensation. The Compensation Committee has authority to determine all compensation applicable to our executive officers. In setting executive compensation for our executive officers, the Compensation Committee considers, among other things, the following factors: each executive's position within the Company and the level of responsibility; the ability of the executive to affect key business initiatives; the executive's individual experience and qualifications; compensation paid to executives of comparable positions by companies similar to our Company; Company and individual performance; and the executive's current and historical compensation levels. The Compensation Committee has also from time to time – including during 2023 – retained the services of an independent consulting firm to provide advice with respect to executive compensation, such as developing a group of comparable peer companies and reviewing executive and director compensation levels. In making decisions regarding the form and amount of compensation to be paid to our executives, the Compensation Committee may consider information gathered by, and the recommendations of, its current outside compensation consultant, Alpine Rewards, when necessary and appropriate.

In making decisions regarding the form and amount of compensation to be paid to our executive officers other than our Chief Executive Officer, the Compensation Committee considers and gives weight to the recommendations of our Chief Executive Officer recognizing that due to his reporting and otherwise close relationship with each executive, the Chief Executive Officer often is in a better position than the Compensation Committee to evaluate the performance of each executive (other than himself). In making decisions regarding the form and amount of compensation to be paid to our Chief Executive Officer, the Compensation Committee considers the recommendation of the Chief Executive Officer with respect to his own compensation and the Compensation Committee's own assessment of the Chief Executive Officer's annual performance and input from other Board members. The Compensation Committee meets in executive session regularly and makes all executive compensation decisions about the Chief Executive Officer without the presence of the Chief Executive Officer or any executive or employee of our Company.

Processes and Procedures for Consideration and Determination of Director Compensation. The Board has delegated to the Compensation Committee the responsibility, among other things, to establish and lead a process for determining compensation payable to our non-employee directors. The Compensation Committee makes recommendations regarding compensation payable to our non-employee directors to the entire Board, which then makes the final decision. In making decisions regarding compensation to be paid to our non-employee directors, the Board considers factors such as its own views as to the form and amount of compensation to be paid, the current and anticipated time demands placed on non-employee directors and other factors that may be relevant, including the recommendations of Alpine Rewards, when necessary and appropriate.

A copy of the Compensation Committee's written charter is publicly available on our website at www.cervomed.com.

Nominating and Corporate Governance Committee

Responsibilities. The primary responsibilities of the Nominating and Corporate Governance Committee are:

- identifying individuals qualified to become Board members;
- recommending director nominees for each annual meeting of our stockholders and director nominees to fill any vacancies that may occur between meetings of stockholders;
- being aware of best practices in corporate governance and developing and recommending to the Board a set of corporate governance standards to govern the Board, its committees, our Company and our employees in the conduct of our business and affairs;
- developing and overseeing a Board and Board committee evaluation process; and
- reviewing and discussing with our Chief Executive Officer and reporting periodically to the Board plans for executive officer development and succession plans for the Chief Executive Officer and other key executive officers and employees.

The Nominating and Corporate Governance Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition. The current members of the Nominating and Corporate Governance Committee are Ms. Hollingsworth, Dr. Sabbagh and Mr. Zavrl. Ms. Hollingsworth is the chair of the Nominating and Corporate Governance Committee. Each of the three current members of the Nominating and Corporate Governance Committee is an "independent director" within the meaning of the Listing Rules of the Nasdaq Capital Market. From January 1, 2023, until the completion of the Merger, Messrs. Adams, Giles and Levin and Dr. Lanchoney were the members of Diffusion's Nominating and Governance Committee, with Mr. Giles serving as chair.

Processes and Procedures for Consideration Director Nominations. In selecting nominees for the Board, the Nominating and Corporate Governance Committee first determines whether the incumbent directors are qualified to serve, and wish to continue to serve, on the Board. The Nominating and Corporate Governance Committee believes that our Company and stockholders benefit from the continued service of certain qualified incumbent directors because those directors have familiarity with and insight into our Company's affairs that they have accumulated during their tenure with CervoMed, in addition to the qualifications and expertise contributing to such director's original appointment to the Board. Appropriate continuity of Board membership also contributes to the Board's ability to work as a collective body. Accordingly, it is the practice of the Nominating and Corporate Governance Committee, in general, to re-nominate an incumbent director at the upcoming annual meeting of stockholders if the director wishes to continue his or her service with the Board, the director continues to satisfy the Nominating and Corporate Governance Committee's criteria for membership on the Board, the Nominating and Corporate Governance Committee believes the director continues to make important contributions to the Board and there are no special, countervailing considerations against re-nomination of the director.

In identifying and evaluating new candidates for election to the Board, the Nominating and Corporate Governance Committee generally first solicits recommendations for nominees from persons whom the Nominating and Corporate Governance Committee believes are likely to be familiar qualified candidates having the qualifications, skills and characteristics required for Board nominees. Such persons may include members of the Board and senior management of CervoMed or other individuals within the personal networks of Company leadership. In addition, the Nominating and Corporate Governance Committee may engage a search firm to assist it in identifying qualified candidates. The Nominating and Corporate Governance Committee then reviews and evaluates each candidate whom it believes merits serious consideration, taking into account available information concerning the candidate, any qualifications or criteria for Board membership established by the Nominating and Corporate Governance Committee, the existing composition of the Board (including with respect to diversity), and other factors that it deems relevant. In conducting its review and evaluation, the Nominating and Corporate Governance Committee may solicit the views of our management, other Board members and any other individuals it believes may have insight into a candidate. The Nominating and Corporate Governance Committee may designate one or more of its members and/or other Board members to interview any proposed candidate.

The Nominating and Corporate Governance Committee will consider recommendations for the nomination of directors submitted by our stockholders. The Nominating and Corporate Governance Committee will evaluate candidates recommended by stockholders in the same manner as those recommended described above.

There are no formal requirements or minimum qualifications that a candidate must meet in order for the Nominating and Corporate Governance Committee to recommend the candidate to the Board. The Nominating and Corporate Governance Committee believes that each nominee should be evaluated based on his or her merits as an individual, taking into account the needs of the Company and the Board. However, in evaluating candidates, there are a number of criteria that the Nominating and Corporate Governance Committee generally views as relevant and is likely to consider. Some of these factors include:

- whether the candidate is an "independent director" under applicable independence tests under the federal securities laws and rules and regulations of the SEC;
- whether the candidate is "financially sophisticated" and otherwise meets the requirements for serving as a member of an audit committee;
- whether the candidate is an "audit committee financial expert" under the rules and regulations of the SEC for purposes of serving as a member of the Audit Committee;
- the needs of the Company with respect to the particular talents and experience of our directors;
- the personal and professional integrity and reputation of the candidate;
- the candidate's level of education and business experience;
- the candidate's business acumen;
- the candidate's level of understanding of our business and industry and other industries relevant to our business;
- the candidate's ability and willingness to devote adequate time to the work of the Board and its committees;
- the fit of the candidate's skills and personality with those of other directors and potential directors in building a board of directors that is effective, collegial and responsive to the needs of our Company;
- whether the candidate possesses strategic thinking and a willingness to share ideas;
- the candidate's diversity of experiences, expertise and background, in general and as compared to other directors on the Board; and
- the candidate's ability to represent the interests of all stockholders and not a particular interest group.

While we do not have a stand-alone diversity policy, in considering whether to recommend any director nominee, including candidates recommended by stockholders, the Nominating and Corporate Governance Committee will consider the factors described above. The Nominating and Corporate Governance Committee seeks nominees with a broad diversity of experience, expertise, and backgrounds. The Nominating and Corporate Governance Committee does not assign specific weights to particular criteria and no particular criterion is necessarily applicable to all prospective nominees. We believe that the backgrounds and qualifications of the directors, considered as a group, should provide a significant mix of experience, knowledge and abilities that will allow the Board to fulfill its responsibilities.

A copy of the Nominating and Corporate Governance Committee's written charter is publicly available on our website at www.cervomed.com.

Board Oversight of Risk

The Board as a whole has responsibility for risk oversight, with more in-depth reviews of certain areas of risk being conducted by the relevant Board committees that report on their deliberations to the full Board. The oversight responsibility of the Board and its committees is enabled by management reporting processes that are designed to provide information to the Board about the identification, assessment and management of critical risks and management's risk mitigation strategies. The areas of risk that we focus on include regulatory, operational, financial (accounting, credit, liquidity and tax), cybersecurity, legal, compensation, competitive, health, safety and environment, economic, political and reputational risks.

The committees of the Board oversee risks associated with their respective principal areas of focus. The Audit Committee's role includes a particular focus on the qualitative aspects of financial reporting to stockholders, our processes for the management of business and financial risk, our financial reporting obligations, cybersecurity and information technology matters, and our compliance with significant applicable legal, ethical and regulatory requirements. The Audit Committee, along with management, is also responsible for developing and participating in a process for review of important financial and operating topics that present potential significant risk to our Company. The Compensation Committee is responsible for overseeing risks and exposures associated with our compensation programs and arrangements, including our executive and director compensation programs and arrangements. The Nominating and Corporate Governance Committee oversees risks relating to our corporate governance matters and policies and management and director succession planning.

We recognize that a fundamental part of risk management is understanding not only the risks a company faces and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for our Company. The involvement of the full Board in setting our business strategy is a key part of the Board's assessment of management's appetite for risk and also a determination of what constitutes an appropriate level of risk for our Company.

We believe our current Board leadership structure is appropriate and helps ensure proper risk oversight for our Company for a number of reasons, including: (1) general risk oversight by the full Board in connection with its role in reviewing our key long-term and short-term business strategies and monitoring on an on-going basis the implementation of our key business strategies; (2) more detailed oversight by our Board committees that are currently comprised of and chaired by our independent directors and (3) the focus of our Chair of the Board and standing committee chairs on allocating appropriate Board and Board committee agenda time for discussion regarding the implementation of our key business strategies and specifically risk management.

Code of Business Conduct and Ethics

Our Code of Business Conduct and Ethics applies to all of our directors, executive officers and other employees, and meets the requirements of the SEC. A copy of our Code of Business Conduct and Ethics is available on the Investor Relations—Corporate Governance—Code of Business Conduct and Ethics section of our corporate website at www.cervomed.com.

Policy Prohibiting Hedging - Insider Trading Policy

We maintain an Insider Trading Policy that prohibits our officers, directors, and employees from, among other things, engaging in speculative transactions in our securities, including by way of the purchase or sale of a put option, a call option or a short sale (including a short sale "against the box"), or engaging in hedging transactions, including prepaid variable forward contracts, equity swaps, collars and exchange funds.

Corporate Governance Guidelines

Our Board has adopted Corporate Governance Guidelines, a copy of which can be found on the Investor Relations—Corporate Governance section of our corporate website at www.cervomed.com. Among the topics addressed in our Corporate Governance Guidelines are:

- Board size, composition and qualifications;
- Selection of directors;
- Board leadership;
- Board committees;
- Board and committee meetings;
- Executive sessions of outside directors;
- Meeting attendance by directors and non-directors;
- Appropriate information and access;
- Ability to retain advisors;
- Conflicts of interest and director independence;
- Board interaction with corporate constituencies;
- Stock ownership by directors and executive officers;
- Retirement and term limits;
- Retirement and resignation policy;
- Board compensation;
- Loans to directors and executive officers;
- Chief Executive Officer evaluation;
- Board and committee evaluations;
- Director continuing education;
- Succession planning;
- Related person transactions;
- Communication with directors;
- Director attendance at annual meetings of stockholders; and
- Change of principal occupation and board memberships.

EXECUTIVE COMPENSATION

Summary Compensation Table

The table below provides summary compensation information concerning compensation awarded for service during the years ended December 31, 2023, and December 31, 2022, to the individuals that served as our NEOs during the year ended December 31, 2023.

Name and Principal Position (1)	Year	Salary (2)	Option Awards (3)	Non-Equity Plan Compensation (4)	All Other Compensation (5)	Total
John Alam, M.D.	2023	$ 472,399	$ 134,900	$ 207,856	$ --	$ 815,155
President & Chief Executive Officer	2022	$ 449,904	$ --	$ 143,969	$ --	$ 593,873
Robert J. Cobuzzi, Jr., Ph.D.	2023	$ 375,000	$ 316,524	$ --	$ 11,600	$ 703,124
Chief Operating Officer (1)	2022	$ 450,000	$ 166,640	$ 202,500	$ 11,600	$ 830,740
Kelly Blackburn, M.H.A.	2023	$ 305,846	$ 60,800	$ 99,094	$ --	$ 465,740
SVP, Clinical Development	2022	$ 263,194	$ --	$ 63,552	$ --	$ 326,746
William Elder	2023	$ 292,782	$ 60,800	$ 114,771	$ --	$ 468,353
General Counsel & Corporate Secretary	2022	$ 292,782	$ 66,643	$ 115,283	$ --	$ 474,708

1) On August 16, 2023, in connection with the completion of the Merger, the Company's executive officers were reconstituted. At the Effective Time of the Merger, (i) Dr. Alam, the President & Chief Executive Officer of EIP, was appointed as the Company's President & Chief Executive Officer, (ii) Dr. Cobuzzi, the President & Chief Executive Officer of Diffusion, was appointed as the Company's Chief Operating Officer, (iii) Ms. Blackburn, the Senior Vice President of Clinical Development of EIP, was appointed as the Company's Senior Vice President of Clinical Development, and (iv) Mr. Elder, the General Counsel & Corporate Secretary of Diffusion, continued as the Company's General Counsel & Corporate Secretary. The amounts set forth in the table include (A) with respect to Dr. Alam and Ms. Blackburn, (x) compensation from EIP for service during the year ended December 31, 2022, and from January 1, 2023 through the completion of the Merger and (y) compensation from the Company for service from the completion of the Merger through December 31, 2023 and (B) with respect to Dr. Cobuzzi and Mr. Elder, (x) compensation from Diffusion for service during the year ended December 31, 2022, and from January 1, 2023 through the completion of the Merger and (y) compensation from the Company for service from the completion of the Merger through December 31, 2023.
2) Represents base salary as described below under "—*Employment Agreements*." From June 2023 to August 2023, Dr. Cobuzzi voluntarily waived his base salary in order to preserve cash resources in advance of the Merger closing.
3) The amounts shown in this column reflect the grant date fair value of option awards granted for service during the applicable year, calculated in accordance with the provisions of ASC Topic 718 and determined without regard to forfeitures. Amounts shown for 2023 include awards with the following grant date fair values: (i) with respect to Dr. Alam, $134,900 granted in September 2023; (ii) with respect to Dr. Cobuzzi, (x) $60,800 granted in September 2023 and (y) $255,724 granted in January 2024 for service during 2023 in lieu of a cash incentive bonus as described below in Footnote 4, and (iii) with respect to Ms. Blackburn and Mr. Elder, in each case, $60,800 granted in September 2023. Amounts shown for 2022 are the grant date fair values of awards to Dr. Cobuzzi and Mr. Elder granted in January 2022. The assumptions used in the Black-Scholes model to determine the grant date fair values of awards granted during the fiscal years ended December 31, 2023, and 2022 are disclosed in Note 12 to the audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 and Note 8 to the audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022, respectively. Assumptions used during the fiscal year ending December 31, 2024, will be disclosed in our Annual Report on Form 10-K for the year ending December 31, 2024.
4) Represents the annual cash incentive bonuses for service during the applicable year by our NEOs as described further below under "—*Cash Bonus Compensation*". For the year ended December 31, 2023, in lieu of an annual cash bonus, Dr. Cobuzzi was awarded an increased option award of substantially similar economic value on the grant date as further described above in Footnote 3.
5) The amounts reported in this column represent 401(k) Plan matching contributions by the Company. Our NEOs also participate in the Company's health, dental, vision and life insurance plans, as well as the Company's health savings account, on the same terms available generally to salaried employees.

Employment Agreements

John Alam, M.D., President & Chief Executive Officer. Effective February 1, 2024, we entered into an amended and restated employment agreement with Dr. Alam pursuant to which he serves as our President and Chief Executive Officer. Dr. Alam's annual base salary for the year ended December 31, 2023 was $472,399 and his target annual bonus was 40 percent of his base salary. Pursuant to the employment agreement, Dr. Alam's initial base salary is $538,534, which amount the Board may increase (but not decrease) at its discretion. The employment agreement also provides Dr. Alam the opportunity to earn a target annual bonus of 50 percent of his base salary. In addition, the employment agreement contains certain severance and change of control provisions as described in more detail under the heading "*—Post-Termination Severance and Change in Control Arrangements*," non-competition and non-solicitation provisions (each applicable during employment and for 24 months thereafter), and confidentiality and non-disparagement provisions (each applicable during employment and at all times thereafter). The employment agreement has an indefinite term.

Robert J. Cobuzzi, Jr., Ph.D., Chief Operating Officer. Effective February 1, 2024, we entered into an amended and restated employment agreement with Dr. Cobuzzi pursuant to which he serves as our Chief Operating Officer. Dr. Cobuzzi's annual base salary for the year ended December 31, 2023, was $450,000 and his target annual bonus was 50 percent of his base salary; from June 2023 to August 2023, Dr. Cobuzzi voluntarily waived his base salary in order to preserve cash resources in advance of the Merger closing. Pursuant to the employment agreement, Dr. Cobuzzi's initial base salary is $465,750, which amount the Board may increase (but not decrease) at its discretion. The employment agreement also provides Dr. Cobuzzi the opportunity to earn a target annual bonus of 50 percent of his base salary. In addition, the employment agreement contains certain severance and change of control provisions as described in more detail under the heading "*—Post-Termination Severance and Change in Control Arrangements*," non-competition and non-solicitation provisions (each applicable during employment and for 24 months thereafter), and confidentiality and non-disparagement provisions (each applicable during employment and at all times thereafter). The employment agreement has an indefinite term.

Kelly Blackburn, M.H.A., Senior Vice President, Clinical Development. Effective February 1, 2024, we entered into an employment agreement with Ms. Blackburn pursuant to which she serves as our Senior Vice President of Clinical Development. Ms. Blackburn's annual base salary for the year ended December 31, 2023, was $305,846 and her target annual bonus was 30 percent of her base salary. Pursuant to the employment agreement. Ms. Blackburn's initial base salary is $316,549, which amount the Board may increase (but not decrease) at its discretion. The employment agreement also provides Ms. Blackburn the opportunity to earn a target annual bonus of 35 percent of her base salary. In addition, the employment agreement contains certain severance and change of control provisions as described in more detail under the heading "*—Post-Termination Severance and Change in Control Arrangements*," non-competition and non-solicitation provisions (each applicable during employment and for 12 and 24 months thereafter, respectively), and confidentiality and non-disparagement provisions (each applicable during employment and at all times thereafter). The employment agreement has an indefinite term and requires Ms. Blackburn to devote no less than approximately 80 percent of her business time and energies to her work for the Company.

William R. Elder, General Counsel & Corporate Secretary. Effective September 23, 2020, we entered into an employment agreement with Mr. Elder, which agreement was amended effective March 29, 2023, pursuant to which he serves as our General Counsel & Corporate Secretary. Mr. Elder's annual base salary under the employment agreement for the year ended December 31, 2023, was $292,782, which amount the Board may increase (but not decrease) at its discretion. The employment agreement also provides Mr. Elder the opportunity to earn a target annual bonus of 30 percent of his base salary; for the year ended December 31, 2023, the Compensation Committee established a target annual bonus of 35 percent of base salary for Mr. Elder. In addition, the employment agreement contains certain severance and change of control provisions as described in more detail under the heading "*—Post-Termination Severance and Change in Control Arrangements*," non-competition and non-solicitation provisions (each applicable during employment and for 24 months thereafter), and confidentiality and non-disparagement provisions (each applicable during employment and at all times thereafter). The employment agreement has an indefinite term.

Cash Bonus Compensation

Each of our executive officers has a target annual cash bonus amount based on a percentage of the executive's annual base salary in the applicable year, as described above under "*—Employment Agreements*." The actual amount of cash bonuses is determined annually by the Compensation Committee. The Compensation Committee determines whether bonuses are earned and the amounts of the bonus payout by considering a number of factors, the principal factor being based upon performance goals developed by the Compensation Committee at the beginning of each year. Important factors that may be considered by the Compensation Committee when developing these performance goals each year or otherwise in determining the amount of executive cash bonus compensation include, among other things, clinical trial progress, business development activities, status of public filings, capital raising transactions, and stock price performance.

Long-Term Equity Incentive Compensation and Other Compensatory Arrangements

The Compensation Committee administers the 2015 Equity Plan in which our NEOs participate, the cash bonus payments made to our NEOs provided for in the employment agreements described under the heading "*—Employment Agreements*," and any other compensation-related matters with respect to our NEOs as they otherwise determine in their discretion. The option grants made for service during 2023 to the NEOs vest and become exercisable in equal monthly installments over a 36-month period until fully vested, subject to the executive's continued employment through the applicable vesting date. The Compensation Committee believes time-based vesting of these awards aligns with the 2015 Equity Plan's purpose of attracting and retaining qualified individuals to perform services for the Company and aligning the interests of such individuals with the interests of our stockholders.

Outstanding Equity Awards at Fiscal Year End

Option Awards

The table below provides information regarding outstanding stock option awards held by each of our NEOs as of December 31, 2023. Unless otherwise indicated, each grant was awarded under our 2015 Equity Plan.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($/share)	Option Expiration Date
John Alam, M.D.	2,760*	22,084	$ 5.33	9/15/2033
	1,184	9,472	$ 5.33	9/15/2033
Robert J. Cobuzzi, Jr., Ph.D.	1,582	-	$ 38.25	1/7/2030
	818	-	$ 75.00	6/17/2030
	6,334	-	$ 59.25	9/8/2030
	677	39	$ 83.25	3/1/2031
	716**	-	$ 83.25	3/1/2031
	6,795	3,397	$ 18.00	1/27/2032
	1,777	14,223	$ 5.33	9/15/2033
Kelly Blackburn, M.H.A.	8,287*	-	$ 19.81	5/28/2028
	5,524*	-	$ 27.72	3/3/2029
	4,604*	-	$ 26.07	12/16/2029
	4,747	2,159	$ 34.84	3/12/2031
	1,777	14,222	$ 5.33	9/15/2033
William R. Elder	934	-	$ 61.50	9/22/2030
	1,104	65	$ 83.25	3/1/2031
	278**	-	$ 83.25	3/1/2031
	2,717	1,359	$ 18.00	1/27/2032
	1,777	14,223	$ 5.33	9/15/2033

* - Granted pursuant to the 2018 Equity Plan, which was assumed by the Company in accordance with and pursuant to the terms of the Merger Agreement.

** - Pursuant to the terms of the corresponding award agreements, two-thirds of the underlying shares originally granted were automatically forfeited on October 1, 2021, due to non-achievement of certain specified performance metrics.

All of the option grants described in the table above granted prior to 2023 pursuant to the 2015 Plan vest and become exercisable in equal monthly installments over a 36-month period until fully vested, subject to the executive's continued employment through the applicable vesting date. All of the option grants described in the table above granted prior to 2023 pursuant to the 2018 Plan vest and become exercisable (i) with respect to 25% of the underlying shares, on the one-year anniversary of the grant date and (ii) with respect to the remaining shares, in equal monthly installments over a 36-month period until fully vested, in each case, subject to the executive's continued employment through the applicable vesting date.

401(k) Retirement Plan

We maintain our 401(k) Plan pursuant to which all eligible employees are entitled to make pre-tax and after-tax contributions of their compensation. In addition, the Company makes discretionary matching contributions at a rate of 100% for contributions up to 3% of the participant's eligible compensation and 50% for any additional contributions up to 5% of the participant's eligible compensation. The matching contributions received by our NEOs in the years ended December 31, 2023, and 2022, are reported in the "All Other Compensation" column of the Summary Compensation Table above.

Post-Termination Severance and Change in Control Arrangements

As described under the heading "—*Employment Agreements*," we have entered into employment agreements with each of our executive officers that provide for certain severance and change of control benefits, subject to the execution and non-revocation of a release of claims by the executive or the executive's estate (as applicable).

Under the employment agreements with each of Drs. Alam and Cobuzzi, in the event that the executive's employment is terminated by us other than for "cause," death or "disability," or is terminated by the executive for "good reason" (as such terms are defined in the applicable employment agreement), the executive will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, continuation of base salary for 12 months, plus 12 months of COBRA premium reimbursement, provided that if such termination occurs within 60 days before or within 24 months following a "change of control" (as defined in the applicable employment agreement), then the executive will be entitled to receive the same severance benefits as described above, except that he will receive (a) a payment equal to two times the sum of his base salary and the higher of his target annual bonus opportunity and the bonus payment he received for the year immediately preceding the year in which the termination occurred instead of 12 months of base salary continuation, and (b) a payment equal to 36 times the monthly COBRA premium for him and his eligible dependents instead of 12 months of COBRA reimbursements (the payments in clauses (a) and (b) are paid in a lump sum in some cases and partly in a lump sum and partly in installments over 12 months in other cases). In addition, if the executive's employment is terminated by us without cause or by the executive for good reason, in either case, upon or within 24 months following a change of control, then the executive will be entitled to full vesting of all equity awards received by him from us (with any equity awards that are subject to the satisfaction of performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 24 months following the termination date (but in no event beyond the expiration date of the applicable option or stock appreciation right)).

Under the employment agreements with each of Ms. Blackburn and Mr. Elder, in the event that the executive's employment is terminated by us other than for "cause", death or "disability" or upon the executive's resignation for "good reason" (as such terms are defined in the applicable employment agreement), the executive will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, continuation of base salary for 9 months, plus 12 months of COBRA premium reimbursement, provided that if such termination occurs within 60 days before or within 24 months following a "change of control" (as defined in the applicable employment agreement), then the executive will be entitled to receive the same severance benefits as described above, except that the executive will receive (a) a payment equal to 1.5 times the sum of their base salary and the higher of their target annual bonus opportunity and the bonus payment received for the year immediately preceding the year in which the termination occurred instead of 9 months of base salary continuation and (b) a payment equal to 18 times the monthly COBRA premium for the executive and the executive's eligible dependents instead of 12 months of COBRA reimbursements (the payments in clauses (a) and (b) are paid in a lump sum in some cases and in installments over 9 or 12 months in other cases). In addition, if the executive's employment is terminated by the Company without cause or by the executive for good reason, in either case, upon or within 24 months following a change of control, then the executive will be entitled to full vesting of all equity awards received by the executive from us (with any equity awards that are subject to the satisfaction of performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 24 months following the termination date (but in no event beyond the expiration date of the applicable option or stock appreciation right)).

Under the employment agreements for each of our current NEOs, in the event that the executive's employment is terminated due to the executive's "death" or "disability," the executive (or the executive's estate) will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, 12 months of COBRA premium reimbursement and accelerated vesting of the greater of the portion of the unvested equity award that would have become vested within 12 months after the termination date had no termination occurred and the portion of the unvested equity award that is subject to accelerated vesting (if any) upon such termination under the applicable equity plan or award agreement (with performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 12 months following the termination date or, if longer, such period as provided under the applicable equity plan or award agreement (but in no event beyond the expiration date of the applicable option or stock appreciation right)).

Further, under the terms of the stock option agreements with our NEOs that were granted under our 2015 Equity Plan, upon a completion of a "change of control" (as defined in the 2015 Equity Plan), options held by our NEOs will become immediately vested and remain exercisable through their expiration date regardless of whether the holder remains in the employment or service of the Company after the change of control. Alternatively, in connection with a change of control, the Compensation Committee may, in its sole discretion, cash out the options.

DIRECTOR COMPENSATION

Overview of Non-Employee Director Compensation Program

As described in more detail under the heading "*Corporate Governance—Compensation Committee—Responsibilities*," the Board has delegated to the Compensation Committee the responsibility to establish and lead a process for the determination of compensation payable to our non-employee directors. The Compensation Committee makes recommendations regarding compensation payable to our non-employee directors to the entire Board, which then makes final decisions regarding such compensation.

The principal elements of our director compensation program for 2023 included:

- cash compensation in the form of annual cash retainers; and
- long-term equity-based incentive compensation, in the form of stock options.

Cash Compensation

The cash compensation paid to the non-employee members of the Board for the term ending at the 2024 annual meeting of stockholders consisted of the following cash retainers, pro-rated for any director serving a partial year term as further described under the heading, "*—Summary Director Compensation Table*."

Description		Annual Cash Retainer
Board Member	$	40,000
Chair of the Board	$	20,000
Audit Committee Chair	$	15,000
Compensation Committee Chair	$	10,000
Nominating and Corporate Governance Committee Chair	$	8,000
Audit Committee Member (other than Chair)	$	7,500
Compensation Committee Member (other than Chair)	$	5,000
Nominating and Corporate Governance Committee Member (other than Chair)	$	4,000

The annual cash retainers are paid in regular installments in accordance with the Company's standard payroll practices. The Compensation Committee has also reserved the right to make a portion of such payments in the form of equity rather than cash under certain conditions. During the fiscal year ended December 31, 2023, all retainers were paid in cash. From June 2023 to August 2023, Diffusion's non-employee directors voluntarily waived all cash compensation in order to preserve cash resources in advance of the Merger closing.

Long-Term Equity-Based Incentive Compensation

In addition to cash compensation, our non-employee directors receive long-term equity-based incentive compensation in the form of options to purchase shares of our common stock. Upon a non-employee director's initial appointment to the Board, the director receives a stock option award exercisable for a number of shares equal to 0.176% of the Company's total shares outstanding on the grant date vesting in 36 equal monthly installments following his or her appointment to the Board. Each non-employee director also receives, on an annual basis, a stock option award exercisable for a number of shares equal to 0.088% of the Company's total shares outstanding on the grant date vesting in 12 equal monthly installments following the grant date.

All option awards granted to our non-employee directors have a ten-year term and an exercise price equal to the fair market value of our common stock on the grant date.

Summary Director Compensation Table

The table below provides summary information concerning the compensation of each individual who served as a non-employee director of the Company during the year ended December 31, 2023. Joshua S. Boger, Ph.D., our current Board Chair, was appointed to the Board and as Chair effective February 7, 2024, and, accordingly, did not receive any compensation for service to the Company during the year ended December 31, 2023.

Our employee directors – Dr. Alam, our President and Chief Executive Officer, and Dr. Cobuzzi, our Chief Operating Officer – do not receive additional compensation for their service on the Board.

Name	Fees Earned or Paid in Cash (1)	Option Awards (2)	All Other Compensation	Total
Robert Adams	$ 24,750	$ --	$ --	$ 33,584
Jill Davidson (3)	$ 10,740	$ 24,510 (4)	$ --	$ 35,250
Mark T. Giles	$ 25,471	$ --	$ --	$ 34,517
Sylvie Grégoire, PharmD.	$ 24,576	$ 24,510	$ 327,856 (5)	$ 376,942
Jane H. Hollingsworth, J.D.	$ 58,395	$ 24,510	$ --	$ 95,583
Diana Lanchoney, M.D.	$ 22,420	$ --	$ --	$ 30,474
Alan Levin	$ 27,042	$ --	$ --	$ 36,694
Jeff Poulton	$ 22,685	$ 24,510	$ --	$ 47,195
Marwan Sabbagh, M.D.	$ 16,636	$ 24,510	$ --	$ 41,146
Frank Zavrl	$ 23,253	$ 24,510	$ --	$ 47,763

1) On August 16, 2023, we completed the Merger. At the Effective Time, in accordance with the terms of the Merger Agreement, (i) each of Messrs. Adams, Giles and Levin and Dr. Lanchoney resigned from the Board and any respective committee memberships, (ii) each of Dr. Grégoire, Mr. Poulton, Dr. Sabbagh and Mr. Zavrl were appointed to the Board, and (iii) each of Ms. Hollingsworth and Ms. Davidson remained on the Board. All cash consideration paid by the Company to non-employee directors during the year ended December 31, 2023, was prorated based on time served. From June 2023 to August 2023, Diffusion's non-employee directors voluntarily waived all cash compensation in order to preserve cash resources in advance of the Merger closing. EIP directors did not receive cash compensation during 2023 prior to completion of the Merger.
2) The amounts shown in this column reflect the grant date fair value of option awards granted in September 2023 to the identified directors, calculated in accordance with the provisions of ASC Topic 718 and determined without regard to forfeitures. See the assumptions used in the Black-Scholes Model in Note 12 to the audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023. The aggregate number of shares subject to options awarded to our non-employee directors during the year ended December 31, 2023, was, in each case, 6,450, of which 716 were vested as of December 31, 2023.
3) Ms. Davidson was appointed to the Board effective July 26, 2023, and resigned from the Board effective November 1, 2023.
4) Effective upon Ms. Davidson's resignation from the Board, all unvested shares underlying the award were cancelled in accordance with the terms of the award agreement for the grant. On November 8, 2023, Ms. Davidson net exercised the vested shares underlying the award and was issued 166 shares of common stock. The remaining 193 vested shares were cancelled in consideration of the aggregate exercise price for such exercise.
5) Includes (i) $227,640 of pro-rated base salary and (ii) a pro-rated annual bonus payment of $100,216, in each case, paid in cash for service as EIP's Executive Board Chair from January 1, 2023, to August 16, 2023, the closing date of the Merger.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2023.

	(a)	(b)	(c)
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (1)	184,214	$ 80.02	12,580(2)
Equity compensation plans not approved by security holders (3)	165,160	$ 19.65	--
Total	349,374	$ 51.48	12,580(2)

(1) Includes securities issued and issuable pursuant to the 2015 Equity Plan.

(2) 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. As of December 31, 2023, there were 12,580 shares available for future issuance under the 2015 Equity Plan. On January 1, 2024, the number of shares available for future issuance under the 2015 Equity Plan increased by 226,981.

(3) Includes securities issued pursuant to the 2018 Equity Plan. Additional information regarding the 2018 Equity Plan is included immediately below.

Summary Description of the Company's Non-Stockholder Approved Equity Compensation Plans

2018 Employee, Director and Consultant Equity Incentive Plan

On March 28, 2018, EIP adopted the 2018 Equity Plan, which was assumed by the Company upon completion of the Merger pursuant to and in accordance with the terms of the Merger Agreement. Under the 2018 Equity 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, with respect to grants made prior to the completion of the Merger, generally vest over a four-year period with 25% of the options vesting after one-year of service and the remainder vesting monthly thereafter; awards granted under the 2018 Plan following the completion of the Merger vest in equal monthly installments over 36 months from the grant date. As of December 31, 2023, there were no shares available for issuance under the 2018 Equity Plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Our Audit Committee is charged with the responsibility of reviewing and approving or ratifying all related person transactions in accordance with the Listing Rules of the Nasdaq Capital Market and other applicable law, rules and regulations and any related policies and procedures adopted by or on behalf of the Company and then in effect.

Since January 1, 2022, there have been no transactions to which we have been a party in which (i) the amount involved in the transaction exceeds $120,000 and (ii) any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock had or will have a direct or indirect material interest, except as set forth below:

Executive and Director Compensation

The employment agreements and other compensation arrangements between the Company, on the one hand, and each of our executive officers and directors, on the other hand, are described above under the headings, "*Executive Compensation*" and "*Director Compensation*".

Indemnification Agreements

Our certificate of incorporation, as amended, states that we will indemnify our directors and executive officers to the fullest extent permitted by Delaware law. In addition, we have entered into customary indemnification agreements with each of our executive officers and directors who serve as officers and directors of the Company.

Pre-Funded Warrant Amendment and Exercise

In connection with the closing of the Merger, the Company issued a pre-funded warrant to the Boger Trust to purchase an aggregate of 495,995 shares of common stock for a purchase price of $0.001 per share. Joshua S. Boger, Ph.D., the Chair of the Board, is the sole trustee of the Boger Trust. On February 26, 2024, the Company and the Boger Trust entered into an amendment to the pre-funded warrant pursuant to which the parties eliminated a limitation restricting any exercise that would otherwise result in the holder's beneficial ownership exceeding 9.99% of the Company's outstanding common stock. Also on February 26, 2024, following the effectiveness of the foregoing amendment, the Boger Trust exercised the pre-funded warrant in full pursuant to the cashless exercise provision in Section 2(c) thereof, including the withholding of shares in lieu of a cash payment of the exercise price, and received 495,959 shares of common stock.

2023 EIP Share Issuance

On July 10, 2023, EIP sold and issued (x) 472,303 shares of EIP Common Stock to Dr. Boger for a total purchase price of $694,286; and (y) 78,717 shares of EIP Common Stock to Frank Zavrl, a member of our Board, for a total purchase price of $115,714. At the Effective Time, each outstanding share of EIP capital stock – including such shares purchased by Dr. Boger and Mr. Zavrl – was converted into the right to receive 0.1151 shares of Company common stock.

Lock-Up Agreements and Waiver

In connection with the closing of the Merger, the Company entered into lock-up agreements with certain individuals, including each executive officer and director of EIP and Diffusion, pursuant to which each such individual accepted certain restrictions on transfers of the shares of the Company for a period of time following the Effective Time. On November 9, 2023, the Company entered into waivers to the lock-up agreements by and between the Company, on the one hand, and each of Dr. Alam, our President and Chief Executive Officer and member of our Board, and Dr. Grégoire, a member of our Board, on the other hand, pursuant to which the Company agreed to waive certain restrictions in the lock-up agreements to permit the gifting of an aggregate of 22,500 shares of common stock to certain friends and families, provided that each such transferee entered into a lock-up agreement with substantially similar restrictions for the remainder of the lock-up period applicable to Dr. Alam and Dr. Grégoire.

In connection with the 2024 Private Placement, the Company entered into lock-up agreements with each of the Company's executive officers and directors pursuant to which each such individual accepted certain restrictions on transfers of the shares of the Company for a period of time following the closing of the 2024 Private Placement.

Convertible Note Amendments

In December 2020, EIP issued the 2020 Notes to predominantly related party investors for aggregate proceeds of $5,078,500. In December 2021, the Company issued the 2021 Notes to predominantly related party investors for aggregate proceeds of $6,000,000. Among the Company's current directors and executive officers: Dr. Alam purchased $500,000 of the 2020 Notes; Dr. Grégoire purchased $500,000 of the 2020 Notes; Dr. Boger and his affiliates purchased an aggregate of $500,000 of the 2020 Notes and $5,000,000 of the 2021 Notes; Mr. Zavrl and his affiliates purchased an aggregate of $350,000 of the 2020 Notes and $1,000,000 of the 2021 Notes; Ms. Blackburn, our Senior Vice President, Clinical Development, purchased an aggregate of $150,000 of the 2020 Notes; and Mr. Poulton, a member of our Board, purchased $100,000 of the 2020 Notes.

In June 2023, EIP and the holders of the EIP Convertible Notes amended the terms and conditions of the EIP Convertible Notes to, among other things, establish a fixed conversion price of $1.47 per share of EIP Common Stock with respect to the Merger. In addition, the 2021 Notes were amended to provide that, to the extent the conversion of such notes in the Merger were to result in the holder beneficially owning more than 9.99% of the outstanding voting stock of the Company, such holder would be granted pre-funded warrants in lieu of common stock for the conversion of any principal and accrued but unpaid interest in excess of 9.99%.

In connection with the closing of the Merger, all outstanding EIP Convertible Notes converted into shares of EIP Common Stock at the fixed conversion price of $1.47 per share of EIP Common Stock, which shares of EIP Common Stock were subsequently converted into the right to receive 0.1151 shares of our common stock (or pre-funded warrants in lieu thereof) upon closing of the Merger.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information, to our knowledge, as of April 29, 2024, regarding the beneficial ownership of our capital stock for:

- each person or group of affiliated persons known by us to be a beneficial owner of more than 5% of our outstanding capital stock;
- each of our directors;
- each of our NEOs; and
- all of our executive officers and directors as a group.

Beneficial ownership of shares is determined under rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Except as noted by footnote, and subject to community property laws where applicable, we believe, based upon the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all capital stock shown as beneficially owned by them. The percentage of beneficial ownership is based upon 8,253,741 shares of Common Stock outstanding as of April 29, 2024. Common Stock subject to options or warrants currently exercisable or exercisable within 60 days of April 29, 2024 are deemed to be outstanding and beneficially owned by the person holding the options for the purposes of computing the percentage of beneficial ownership of that person and any group of which that person is a member, but are not deemed outstanding for the purpose of computing the percentage of beneficial ownership for any other person. Unless otherwise indicated, the address for each holder listed below is c/o CervoMed Inc., 20 Park Plaza, Suite 424, Boston, MA 02116.

Name and Address of Beneficial Owner	Number of Shares (1)	Percentage of Total Voting Power (2)
Current Directors and Director Nominees		
John Alam, M.D., *President, Chief Executive Officer & Director* (3)	1,476,995	17.9%
Joshua S. Boger, Ph.D., *Chair of the Board* (4)	1,058,379	12.8%
Robert J. Cobuzzi, Ph.D., *Chief Operating Officer & Director* (5)	31,757	*
Sylvie Grégoire, PharmD., *Director* (6)	1,476,995	17.9%
Jane H. Hollingsworth, J.D., *Director* (7)	4,633	*
Jeff Poulton, *Director* (8)	32,219	*
Marwan Sabbagh, M.D., *Director* (9)	4,745	*
Frank Zavrl, *Director* (10)	368,784	4.5%
Executive Officers (other than Drs. Alam & Cobuzzi)		
Kelly Blackburn, M.H.A., *Sr. Vice President, Clinical Development* (11)	45,041	*
William Elder, *General Counsel & Corporate Secretary* (12)	12,285	*
J. William Tanner, Ph.D., *Chief Financial Officer* (13)	12,445	*
All Directors, Director Nominees, and Executive Officers as a Group (11 persons) (14)	3,047,280	36.3%
Other 5% Stockholders:		
RA Capital Healthcare Fund L.P. (15)	825,373	9.9%
Funds affiliated with Special Situations (16)	810,330	9.9%
Armistice Capital, LLC (17)	734,363	8.9%

* Less than one percent of the outstanding capital stock.

1) Includes shares of Common Stock held as of April 29, 2024 plus shares of Common Stock that may be acquired upon exercise of options, warrants and other rights exercisable within 60 days of April 29, 2024.
2) Based on an estimated 8,253,714 shares of Common Stock issued and outstanding as of April 29, 2024. The percentage ownership and voting power for each person (or all directors and executive officers as a group) is calculated by assuming (i) the exercise or conversion of all options, warrants and convertible securities exercisable or convertible within 60 days of April 29, 2024 held by such person and (ii) the non-exercise and non-conversion of all outstanding warrants, options and convertible securities held by all other persons (including our other directors and executive officers).
3) Consists of (a) 1,461,578 shares of Common Stock held jointly by Dr. Alam and Dr. Grégoire, his spouse, (b) 13,804 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024 held by Dr. Alam and (c) 1,612 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024 held by Dr. Grégoire. Dr. Alam disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.

4) Consists of (a) 216,817 shares of Common Stock held directly by Dr. Boger, (b) 644,703 shares of Common Stock held by The Joshua S. Boger 2021 Trust DTD 12/09/2021 ("JSB 2021 Trust"), (c) 195,748 shares of Common Stock held by The Amy S. Boger 2021 Trust ("ASB 2021 Trust"), and (d) 1,111 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024. Dr. Boger is the sole trustee of the JSB 2021 Trust and the ASB 2021 Trust and may be deemed to be the beneficial owner of such securities. Dr. Boger disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.
5) Consists of (a) 1,078 shares of Common Stock held directly by Dr. Cobuzzi and (b) 30,679 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
6) Consists of (a) 1,461,578 shares of Common Stock held jointly by Dr. Grégoire and Dr. Alam, her spouse, (b) 1,612 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024 held by Dr. Grégoire, and (c) 13,804 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024 held by Dr. Alam. Dr. Grégoire disclaims beneficial ownership of such securities except to the extent of her pecuniary interest therein.
7) Consists of (a) 462 shares of Common Stock held directly by Ms. Hollingsworth, (b) 437 shares of Common Stock held jointly by Ms. Hollingsworth with her spouse, and (c) 3,734 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024. Ms. Hollingsworth disclaims beneficial ownership of such securities except to the extent of her pecuniary interest therein.
8) Consists of (a) 16,444 shares of Common Stock held directly by Mr. Poulton and (b) 15,775 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
9) Consists of 4,745 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
10) Consists of (a) 28,345 shares of Common Stock held by Mr. Zavrl through an individual retirement account, (b) 153,130 shares of Common Stock held by The FEZ Delaware Dynasty Trust ("FEZ Trust"), (c) 171,534 shares of Common Stock held by the Paula Zavrl Delaware Dynasty Trust ("PZ Trust"), and (d) 15,775 shares of common stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024. Mr. Zavrl is the trust investment manager of the FEZ Trust and the PZ Trust and may be deemed to be the beneficial owner of such securities. Mr. Zavrl disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.
11) Consists of (a) 13,674 shares of Common Stock held directly by Ms. Blackburn and (b) 31,367 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
12) Consists of (a) 267 shares of Common Stock held directly by Mr. Elder and (b) 12,018 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
13) Consists of 12,445 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
14) Includes 143,063 shares of Common Stock issuable upon the exercise of options exercisable within 60 days of April 29, 2024.
15) Shares beneficially owned are based solely on the Schedule 13G with the SEC by RA Capital Management, L.P. ("RA Capital") on April 11, 2024. RA Capital directly holds (i) 817,120 shares of common stock; (ii) Pre-Funded Warrants exercisable for up to 449,023 shares of common stock; and (iii) Series A Warrants exercisable for up to 1,266,143 shares of Common Stock. The warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. RA Capital is currently prohibited from exercising the warrants to the extent that such exercise would result in its beneficial ownership of more than 825,373 shares of common stock. RA Capital Management, L.P. (the "Adviser") is the investment manager for the selling stockholder. The general partner of the Adviser is RA Capital Management GP, LLC (the "Adviser GP"), of which Dr. Peter Kolchinsky and Mr. Rajeev Shah are the managing members. The Adviser, the Adviser GP, Dr. Kolchinsky and Mr. Shah disclaim beneficial ownership of any of the securities, except to the extent of their pecuniary interest therein. The principal business address of the selling stockholder is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.
16) Shares beneficially owned by funds affiliated with Special Situations ("Special Situations") are based solely on the on the Company's Current Report on Form 8-K filed with the SEC on March 28, 2024 (the "Closing 8-K"). Special Situations directly holds (i) 405,165 shares of Common Stock and (ii) Series A Warrants exercisable for up to 405,165 shares of common stock. The Series A Warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling shareholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. The address of Special Situations is 527 Madison Avenue, Suite 2600, New York, NY 10022.
17) Shares directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund") and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The Master Fund directly holds (i) 734,363 shares of Common Stock, (ii) Series A Warrants exercisable for up to 734,363 shares of Common Stock and (iii) warrants originally issued in May 2019 exercisable for up to 5,852 shares of Common Stock. The warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Master Fund from exercising that portion of the warrants that would result in the Master Fund and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

SELLING STOCKHOLDERS

This prospectus covers the possible resale from time to time by the selling stockholders identified in the table below of Common Stock, including Common Stock issuable upon the exercise of the Pre-Funded Warrants and Series A Warrants (referred to in this section collectively and individually as the "warrants") issued in the 2024 Private Placement. The selling stockholders may sell some, all or none of their Common Stock. We do not know how long the selling stockholders will hold the warrants, whether any will exercise the warrants, and upon such exercise, how long such selling stockholders will hold the Common Stock before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the Common Stock by each of the selling stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholders, based on its ownership of Common Stock and warrants to purchase Common Stock, as of April 29, 2024, assuming exercise of the warrants held by the selling stockholders on that date, without regard to any limitations on conversions or exercises. The third column lists the maximum number of shares of Common Stock being offered in this prospectus by the selling stockholders. The fourth and fifth columns list the number of shares of Common Stock owned after the offering, by number of shares of Common Stock and percentage of outstanding shares of Common Stock, assuming in both cases the sale of all of the shares of Common Stock offered by the selling stockholders pursuant to this prospectus, and without regard to any limitations on conversions or exercises.

Under the terms of the warrants, a selling stockholder may not exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding shares of Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such warrants which have not been exercised. The beneficial ownership limitation may be increased or decreased, provided that in no event shall it exceed 9.99%, upon notice to us, provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following the receipt of such notice by us. The number of shares in the table below does not reflect this limitation. See "*Plan of Distribution*."

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares Common Stock Beneficially Owned After Offering	Percentage of Shares of Common Stock Owned After Offering
Armistice Capital, LLC (1)	1,474,578	1,468,726	5,852	--
RA Capital Healthcare Fund, L.P. (2)	2,532,286	2,532,286	--	--
Soleus Capital Master Fund, L.P. (3)	253,228	253,228	--	--
Special Situations Cayman Fund, L.P. (4)	137,496	137,496	--	--
Special Situations Fund III QP, L.P. (5)	470,252	470,252	--	--
Special Situations Life Sciences Fund, L.P. (6)	202,582	202,582	--	--

* Less than 1%.

(1) The selling stockholder holds (i) 734,363 shares of Common Stock issued in the 2024 Private Placement and which we are registering hereby, (ii) Series A Warrants to purchase an aggregate of 734,363 shares of Common Stock issued in the 2024 Private Placement and which we are registering hereby and (iii) warrants originally issued in May 2019 to purchase an aggregate of 5,852 shares of Common Stock (the "2019 Warrants"). The warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of Common Stock in excess of the beneficial ownership limitation. Shares directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund") and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(2) The selling stockholder holds (i) 817,120 shares of Common Stock, (ii) Pre-Funded Warrants to purchase an aggregate of 449,023 shares of Common Stock, and (iii) Series A Warrants to purchase an aggregate of 1,266,143 shares of Common Stock, all of which were issued in the 2024 Private Placement and which we are registering hereby. The warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. RA Capital Management, L.P. (the "Adviser") is the investment manager for the selling stockholder. The general partner of the Adviser is RA Capital Management GP, LLC (the "Adviser GP"), of which Dr. Peter Kolchinsky and Mr. Rajeev Shah are the managing members. The Adviser, the Adviser GP, Dr. Kolchinsky and Mr. Shah disclaim beneficial ownership of any of the securities, except to the extent of their pecuniary interest therein. The principal business address of the selling stockholder is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(3) The selling stockholder holds (i) 126,614 shares of Common Stock and (ii) Series A Warrants to purchase an aggregate of 126,614 shares of Common Stock, each of which were issued in the 2024 Private Placement and which we are registering hereby. The Series A Warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling shareholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. The amounts and percentages in the table do not give effect to the 9.99% beneficial ownership limitation, if applicable. The shares of Common Stock reflected in this table are held directly by Soleus Capital Master Fund, L.P. ("Soleus Master Fund"). Soleus Capital, LLC ("Soleus Capital") is the sole general partner of Soleus Master Fund and thus holds voting and dispositive power over the securities held by Soleus Master Fund. Soleus Capital Group, LLC ("SCG") is the sole managing member of Soleus Capital. Mr. Guy Levy is the sole managing member of SCG. Each of SCG, Soleus Capital and Mr. Guy Levy disclaims beneficial ownership of these securities held by Soleus Master Fund, except to the extent of their respective pecuniary interests therein. The principal business address of the selling stockholder is 104 Field Point Road, 2nd Floor, Greenwich, Connecticut 06830.

(4) The selling stockholder holds (i) 68,748 shares of Common Stock and (ii) Series A Warrants to purchase an aggregate of 68,748 shares of Common Stock, each of which were issued in the 2024 Private Placement and which we are registering hereby. The Series A Warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling shareholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. The amounts and percentages in the table do not give effect to the 9.99% beneficial ownership limitation, if applicable. AWM Investment Company Inc. ("AWM") is the investment adviser to and SSCayman LLC ("SSCayman") is the General Partner of the Special Situations Cayman Fund, L.P. David Greenhouse and Adam Stettner are the principal owners of AWM and members of SSCayman. Through their control of AWM, Messrs. Greenhouse and Stettner share voting and investment control. Messrs. Greenhouse and Stettner disclaim any beneficial ownership of the reported shares other than to the extent of any pecuniary interest each of them may have therein. The principal business address of the selling stockholder is 527 Madison Avenue, Suite 2600, New York, NY 10022.

(5) The selling stockholder holds (i) 235,126 shares of Common Stock and (ii) Series A Warrants to purchase an aggregate of 235,126 shares of Common Stock, each of which were issued in the 2024 Private Placement and which we are registering hereby. The Series A Warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling shareholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. The amounts and percentages in the table do not give effect to the 9.99% beneficial ownership limitation, if applicable. AWM is the investment adviser to and MGP Limited Partnership ("MGP") is the General Partner of the Special Situations Fund III QP, L.P. David Greenhouse and Adam Stettner are the principal owners of AWM and members of MGP. Through their control of AWM, Messrs. Greenhouse and Stettner share voting and investment control. Messrs. Greenhouse and Stettner disclaim any beneficial ownership of the reported shares other than to the extent of any pecuniary interest each of them may have therein. The principal business address of the selling stockholder is 527 Madison Avenue, Suite 2600, New York, NY 10022.

(6) The selling stockholder holds (i) 126,614 shares of Common Stock and (ii) Series A Warrants to purchase an aggregate of 126,614 shares of Common Stock, each of which were issued in the 2024 Private Placement and which we are registering hereby. The Series A Warrants are subject to a beneficial ownership limitation of 9.99%, which does not permit the selling stockholder to exercise that portion of the warrants that would result in the selling shareholder and its affiliates owning, after exercise, a number of shares of our Common Stock in excess of the beneficial ownership limitation. The amounts and percentages in the table do not give effect to the 9.99% beneficial ownership limitation, if applicable. AWM is the investment adviser to and LS Advisers LLC ("LSA") is the General Partner of the Special Situations Life Sciences Fund, L.P. David Greenhouse and Adam Stettner are the principal owners of AWM and members of LSA. Through their control of AWM, Messrs. Greenhouse and Stettner share voting investment and control. Messrs. Greenhouse and Stettner disclaim any beneficial ownership of the reported shares other than to the extent of any pecuniary interest each of them may have therein. The principal business address of the selling stockholder is 527 Madison Avenue, Suite 2600, New York, NY 10022.

PLAN OF DISTRIBUTION

Each selling stockholder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of Common Stock (including any Common Stock issuable upon the exercise of Pre-Funded Warrants and/or Series A Warrants) covered by this prospectus on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- sales pursuant to Rule 144;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may sell all or a portion of the shares of Common Stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions, and such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the Common Stock, the warrants or shares of Common Stock they acquire upon the exercise of Pre-Funded Warrants and/or Series A Warrants owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer participating in the distribution of the shares of Common Stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of Common Stock by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of Common Stock to engage in market-making activities with respect to the shares of Common Stock. All of the foregoing may affect the marketability of the shares of Common Stock and the ability of any person or entity to engage in market-making activities with respect to the shares of Common Stock.

We will pay all expenses of the registration of the shares of Common Stock (including Common Stock issuable upon exercise of the Pre-Funded Warrants and/or Series A Warrants) pursuant to the Purchase Agreement, estimated to be $225,408 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

Capitalization

Our authorized capital stock consists of 1,000,000,000 shares of Common Stock and 30,000,000 shares of preferred stock, par value $0.001 per share, all of which remains undesignated.

Common Stock

The following description is based on relevant portions of the DGCL and our Charter. This summary is a description of the material terms of, and is qualified in its entirety by, reference to the Charter.

Authorized. We are authorized to issue 1,000,000,000 shares of Common Stock. We may, from time-to-time, amend our Charter to increase the number of authorized shares of Common Stock. Any such amendment would require the approval of the holders of a majority of the voting power of the shares entitled to vote thereon.

Voting Rights. For all matters submitted to a vote of stockholders, each holder of Common Stock is entitled to one vote for each share registered in the holder's name on the Company's books. Our Common Stock does not have cumulative voting rights. Pursuant to our Bylaws, at all meetings of stockholders, except where otherwise provided by law, our Charter, or our Bylaws, the presence, virtually or by proxy duly authorized, of the holders of 33.4% of the outstanding shares of Common Stock entitled to vote constitutes a quorum for the transaction of business. Except as otherwise provided by law, our Charter or our Bylaws, in all matters other than the election of directors, the affirmative vote of the majority of shares of Common Stock present virtually or by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by law, our Charter or our Bylaws, directors are elected by a plurality of the votes of the shares of Common Stock present virtually or by proxy at the meeting and entitled to vote generally on the election of directors.

Dividends. Subject to limitations under Delaware law and any preferences that may be applicable to any then outstanding preferred stock, holders of Common Stock are entitled to receive ratably those dividends, if any, as may be declared by our board of directors out of legally available funds.

Liquidation. Upon the Company's liquidation, dissolution or winding up, the holders of Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of the company, subject to any prior rights of any preferred stock then outstanding.

Fully Paid and Non-assessable. All shares of outstanding Common Stock are fully paid and non-assessable and any additional shares of Common Stock that the Company issues will be fully paid and non-assessable.

Other Rights and Restrictions. Holders of our Common Stock do not have preemptive or subscription rights, and they have no right to convert their Common Stock into any other securities. There are no redemption or sinking fund provisions applicable to our Common Stock. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of preferred stock which the Company may designate in the future. Neither our Charter nor our Bylaws restrict the ability of a holder of our Common Stock to transfer the holder's shares of Common Stock.

Listing. Our Common Stock is quoted on the Nasdaq Capital Market under the symbol "CRVO."

Transfer Agent and Registrar. The transfer agent and registrar for our Common Stock is Computershare Trust Company, N.A.

Preferred Stock

Our Charter authorizes our board of directors to provide for the issuance of up to 30,000,000 shares of preferred stock in one or more series. Our board of directors is authorized to classify or reclassify any unissued portion of our authorized shares of preferred stock to provide for the issuance of shares of other classes or series, including preferred stock in one or more series. We may issue preferred stock from time to time in one or more classes or series, with the exact terms of each class or series established by our board. Without seeking stockholder approval, our board of directors may issue preferred stock with voting and other rights that could adversely affect the voting power of the holders of our Common Stock. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our Common Stock.

The rights, preferences, privileges and restrictions of the preferred stock of each series will be fixed by the certificate of designation relating to each series, which will specify the terms of the preferred stock, including, but not limited to:

- the distinctive designation and the maximum number of shares in the series;
- the terms on which dividends, if any, will be paid;

- the voting rights, if any, on the shares of the series;
- the terms and conditions, if any, on which the shares of the series shall be convertible into, or exchangeable for, shares of any other class or classes of capital stock;
- the terms on which the shares may be redeemed, if at all;
- the liquidation preference, if any; and
- any or all other preferences, rights, restrictions, including restrictions on transferability, and qualifications of shares of the series.

The issuance of preferred stock may delay, deter or prevent a change in control. No shares of preferred stock are issued or outstanding, and the Company has no present plan to issue any shares of preferred stock.

Pre-Funded Warrants and Series A Warrants

Each Pre-Funded Warrant has an exercise price of $0.001 per Warrant Share, was immediately exercisable on the date of issuance, and will not expire. Under the terms of the Pre-Funded Warrants, the Company may not effect the exercise of any portion of any Pre-Funded Warrant, and a holder will not have the right to exercise any portion of any Pre-Funded Warrant, which, upon giving effect to such exercise, would cause a holder (together with its affiliates) to own more than a specified beneficial ownership limitation of either 4.99% or 9.99% (as selected by such holder prior to the issuance of the Pre-Funded Warrant) of the number of shares of common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to the Company.

The Series A Warrants have an exercise price equal to $39.24 per Warrant Share, representing a 100% premium to the price of last sale, are exercisable immediately and will expire at the earlier of (i) April 1, 2027 or (ii) 180 days after the date that the Company makes a public announcement of positive top-line data from the Company's Phase 2b RewinD-LB clinical trial evaluating neflamapimod for treatment of patients with DLB. Under the terms of the Series A Warrants, the Company may not effect the exercise of any portion of any Series A Warrant, and a holder will not have the right to exercise any portion of any Series A Warrant, which, upon giving effect to such exercise, would cause a holder (together with its affiliates) to own more than a specified beneficial ownership limitation of either 4.99% or 9.99% (as selected by such holder prior to the issuance of the Series A Warrant) of the number of shares of common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Series A Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to the Company.

The exercise price and the number of Warrant Shares will be subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock.

In the event of certain fundamental transactions (as described in the Pre-Funded Warrants), a holder of Pre-Funded Warrants or Series A Warrants, respectively, will have the right to receive, upon exercise of the Pre-Funded Warrants or Series A Warrants, respectively, the same amount and kind of securities, cash or property that such holder would have received had they exercised in full the Pre-Funded Warrants or Series A Warrants, respectively, immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the Pre-Funded Warrants or Series A Warrants, respectively.

Registration Rights

The selling stockholders are entitled to rights with respect to registration of the shares of Common Stock held by it or issuable to it under the Securities Act. These rights are provided under the terms of the Purchase Agreement. The Purchase Agreement requires the Company to file a resale registration statement (the "Resale Registration Statement") with respect to the maximum number of shares of Common Stock held by or issuable to the selling stockholders pursuant to the Equity Warrants and the Exchange Warrants (the "Registrable Securities") within 15 business days after a demand for registration is made pursuant to the Registration Rights Agreement.

Subject to limited exceptions, if the Company fails to file and obtain and maintain effectiveness of the Resale Registration Statement(s) required under the registration rights agreement, then the Company shall be obligated to pay to each affected holder of Registrable Securities an amount equal to 1.5% of the aggregate purchase price of such holder's Registrable Securities whether or not included in such Resale Registration Statement on the date of such failure and 1.5% on every thirtieth day thereafter (pro-rated for periods of less than 30 days) until the date such failure is cured.

Indemnification

The registration rights granted in the registration rights agreement are subject to customary cross-indemnification and contribution provisions, under which we are obligated to indemnify holders of Registrable Securities in the event of material misstatements or omissions in the Resale Registration Statement(s) attributable to the Company, and they are obligated to indemnify the Company in an amount not to exceed the net proceeds to such holder as a result of the sale of Registrable Securities pursuant to such registration statement for material misstatements or omissions in the Resale Registration Statement(s) attributable to them in reliance upon and in conformity with written information furnished to the Company by such holders expressly for use in connection with such Registration Statement.

Expiration of Registration Rights

The Company must use its reasonable best efforts to maintain the effectiveness of the Resale Registration Statement until the earlier of (i) the date as of which the selling stockholder may sell all of the Registrable Securities covered by the applicable Resale Registration Statement(s) without restriction or limitation pursuant to Rule 144 and without the requirement to be in compliance with Rule 144(c)(1) (or any successor thereto) or (ii) the date on which the selling stockholder has sold all of the Registrable Securities covered by the applicable Resale Registration Statement(s).

Anti-Takeover Provisions of our Charter, our Bylaws and Delaware Law

Our Charter and our Bylaws impose certain anti-takeover provisions and make the Delaware Chancery Court the exclusive forum for certain stockholder actions, which may make the acquisition of the Company, a proxy contest, or the nomination of a director candidate by a stockholder more difficult than such actions would be in the absence of such provisions. These provisions include the items described below.

Filling Vacancies

Our Bylaws provide that only our board of directors has the right to fill a vacancy on the board of directors created by an expansion or by the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on the board of directors.

Meetings of Stockholders

Our Bylaws provide that only the Chair of our board of directors, our Chief Executive Officer, or a majority of our directors are authorized to call a special meeting of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Preferred Stock

Our Charter provides for 30,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of the Company's stockholders, our board of directors may issue undesignated preferred stock without stockholder approval in one or more private offerings or other transactions, the terms of which may be established and shares of which may be issued without stockholder approval (notwithstanding any requirements imposed by the SEC or any exchange on which our Common Stock may now or in the future trade), which may include rights superior to the rights of the holders of our Common Stock and which may dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Charter grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of our Common Stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of the Company.

Amendment to Our Bylaws

Our Bylaws may be amended, restated, or repealed by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the Bylaws, and may also be amended by the affirmative vote of 66 2/3% of the outstanding shares entitled to vote on the amendment.

Advance Notice Requirements

Our Bylaws establish advance notice procedures with respect to any nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at any meeting of stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our Secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days (or, if we call a special meeting of stockholders for the purpose of electing one or more directors to our board of directors, not later than the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by our board of directors to be elected at such meeting) nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our Bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Choice of Forum

Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for certain actions, including derivative actions brought on the Company's behalf, stockholder actions claiming breaches of a fiduciary duty owed by any of our directors or officers, and claims arising under our organizational documents, in each case, subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Although this provision would not apply to any stockholder claims under the Exchange Act, there is uncertainty regarding whether a court would enforce such a forum selection provision as written to stockholder claims under the Securities Act. Nevertheless, this forum selection provision may limit our stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers, employees, or agents, which may discourage lawsuits against the Company and such persons. The limitations on certain stockholder rights imposed by these provisions could also depress the trading price of our Common Stock.

Delaware Anti-Takeover Law

The Company is subject to Section 203 of the DGCL. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers of the corporation and (b) shares issued under employee stock plans under which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

LEGAL MATTERS

Certain legal matters in connection with the validity of the securities offered hereby will passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C., Boston, Massachusetts.

EXPERTS

The consolidated financial statements of CervoMed Inc. as of December 31, 2023 and 2022, and for each of the years then ended, have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern), and included in this registration statement, including the accompanying prospectus, in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers the securities covered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our securities, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We file our annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at w*ww.sec.gov*.

The SEC maintains an internet site (*http://www.sec.gov*) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Our website address is *www.cervomed.com*. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

CERVOMED INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of CervoMed Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CervoMed Inc. and its subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations since inception and will be required to raise additional capital to fund operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Accounting for Reverse Recapitalization

As discussed in Note 4 of the accompanying financial statements, on August 16, 2023, EIP Pharma, Inc. ("EIP") merged with Merger Sub, a wholly-owned subsidiary of Diffusion Pharmaceuticals Inc. ("Diffusion"), whereby EIP became the surviving entity and a wholly-owned subsidiary of Diffusion ("the Merger"). Immediately following the Merger, the Company changed its name to CervoMed Inc. ("the Company"). The Merger was accounted for as a reverse recapitalization under the United States generally accepted accounting principles ("U.S. GAAP"), in which EIP was determined to be the accounting acquirer based upon the terms of the Merger and other certain factors.

We identified the accounting for the reverse recapitalization as a critical audit matter because of the complexity in the determination of the proper treatment of the transaction in accordance with U.S. GAAP, including judgments made by management to arrive at the proper conclusion. This required subjective auditor judgment and increased level of effort when performing audit procedures, including the involvement of professionals with specialized skills and knowledge.

Our audit procedures related to the Company's accounting for the reverse recapitalization included the following, among others:

- Obtained the relevant agreements and compared the underlying terms and conditions to management's analysis and supporting documentation.
- With assistance from professionals with specialized skills and knowledge, obtained and evaluated management's analysis and conclusions regarding the accounting treatment of the transaction, including determination of the accounting acquirer and whether the acquiree was considered to be a business.
- Tested the conversion of shares in common stock of the Company, including the conversion of EIP convertible notes and preferred stock and the recalculation of shares issued to Diffusion shareholders.

/s/ RSM US LLP

We have served as the Company's auditor since 2017.

Boston, Massachusetts
March 29, 2024

CervoMed Inc.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,792,846	$ 4,093,579
Prepaid expenses	1,256,501	64,127
Grant receivable	915,404	-
Total current assets	9,964,751	4,157,706
Other assets	7,770	-
Total assets	$ 9,972,521	$ 4,157,706
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 662,471	$ 97,302
Accrued expenses and other current liabilities	1,933,276	644,252
Convertible notes	-	12,414,000
Total liabilities	2,595,747	13,155,554
Commitments and Contingencies (Note 10)		
Convertible preferred stock:		
Series A preferred stock $0.001 par value; 30,000,000 and 0 shares authorized at December 31, 2023 and 2022, respectively, 0 shares issued and outstanding at December 31, 2023 and December 31, 2022	-	-
Series A-1 preferred stock, $0.001 par value; 0 and 1,960,600 shares authorized at December 31, 2023 and 2022, respectively; 0 and 1,960,600 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	-	246,849
Series A-2 preferred stock, $0.001 par value; 0 and 335,711 shares authorized at December 31, 2023 and 2022, respectively; 0 and 335,711 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	-	4,173,267
Series B preferred stock, $0.001 par value; 0 and 1,034,890 shares authorized at December 31, 2023 and 2022, respectively; 0 and 1,034,890 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	-	19,867,095
Total convertible preferred stock	-	24,287,211
Stockholders' Equity (Deficit):		
Common stock, $0.001 par value: 1,000,000,000 and 4,163,600 shares authorized as of December 31, 2023 and 2022, respectively, 5,674,520 and 518,140 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	5,674	518
Additional paid-in capital	61,811,889	18,983,339
Accumulated deficit	(54,440,789)	(52,268,916)
Total stockholders' equity (deficit)	$ 7,376,774	(33,285,059)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 9,972,521	$ 4,157,706

See accompanying notes to the consolidated financial statements

CervoMed Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2023	**2022**
Grant revenue	$ 7,144,872	$ -
Operating expenses:		
Research and development	8,438,499	1,336,469
General and administrative	6,519,268	2,139,065
Total operating expenses	14,957,767	3,475,534
Loss from operations	(7,812,895)	(3,475,534)
Other income (expense):		
Other income (expense)	5,421,592	(2,389,152)
Interest income	219,430	62,226
Interest expense	-	(587)
Total other income (expense)	5,641,022	(2,327,513)
Net loss	$ (2,171,873)	$ (5,803,047)
Per share information:		
Net loss per share of common stock - basic and diluted	$ (0.82)	$ (11.20)
Weighted average shares outstanding - basic and diluted	2,661,416	518,140

See accompanying notes to the consolidated financial statements

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

	Years Ended December 31, 2023 and 2022										
	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2022	1,960,600	246,849	335,711	4,173,267	1,034,890	19,867,095	518,140	518	18,521,988	(46,465,869)	(27,943,363)
Stock-based compensation expense	-	-	-	-	-	-	-	-	333,835	-	333,835
Contributed capital in lieu of executive compensation	-	-	-	-	-	-	-	-	127,516	-	127,516
Net loss	-	-	-	-	-	-	-	-	-	(5,803,047)	(5,803,047)
Balance at January 1, 2023	1,960,600	$ 246,849	335,711	$ 4,173,267	1,034,890	$ 19,867,095	518,140	$ 518	$ 18,983,339	$ (52,268,916)	$ (33,285,059)
Conversion of convertible preferred stock to common stock	(1,960,600)	(246,849)	(335,711)	(4,173,267)	(1,034,890)	(19,867,095)	2,936,566	2,937	24,284,274	-	24,287,211
Issuance of common stock upon settlement of Convertible Notes	-	-	-	-	-	-	795,905	796	6,988,953	-	6,989,749
Issuance of common stock to Diffusion stockholders in reverse recapitalization, net of issuance costs	-	-	-	-	-	-	1,360,244	1,360	10,337,754	-	10,339,114
Sale of common stock	-	-	-	-	-	-	63,422	63	809,937	-	810,000
Stock-based compensation expense, including vesting of RSUs	-	-	-	-	-	-	77	-	407,632	-	407,632
Issuance of common stock from exercises of stock options	-	-	-	-	-	-	359	-	-	-	-
Repurchase of common stock from net settled stock option	-	-	-	-	-	-	(193)	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	(2,171,873)	(2,171,873)
Balance at December 31, 2023	-	$ -	-	$ -	-	$ -	5,674,520	$ 5,674	$ 61,811,889	$ (54,440,789)	$ 7,376,774

See accompanying notes to the consolidated financial statements

CervoMed Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (2,171,873)	$ (5,803,047)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	407,632	333,835
Capital in lieu of executive compensation	-	127,516
Change in fair value of convertible debt	(5,424,251)	2,389,000
Changes in operating assets and liabilities:		
Prepaid expenses, deposits and other assets	(1,200,144)	85,104
Grant receivable	(915,404)	-
Accounts payable	565,169	79,154
Acccrued expenses and other liabilities	1,289,024	215,679
Net cash used in operating activities	(7,449,847)	(2,572,759)
Net assets assumed in connection with reverse recapitalization	11,887,757	-
Proceeds from sale of common stock	810,000	-
Payment of reverse recapitalization costs	(1,548,643)	-
Net cash provided by financing activities	11,149,114	-
Net increase (decrease) in cash and cash equivalents	3,699,267	(2,572,759)
Cash and cash equivalents at beginning of year	4,093,579	6,666,338
Cash and cash equivalents at end of year	$ 7,792,846	$ 4,093,579
Supplemental disclosure of non-cash financing activities:		
Conversion of Convertible Notes	$ 6,989,749	$ -
Conversion of convertible preferred stock	$ 24,287,211	$ -

See accompanying notes to the consolidated 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 biotechnology company developing treatments for age-related neurologic disorders. The Company is currently developing its product candidate neflamapimod, an investigational orally administered small molecule brain penetrant that inhibits p38α. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in DLB and certain other major neurological disorders and is currently being evaluated in a Phase 2b study in patients with DLB.

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

On August 16, 2023, Diffusion approved a one-for-1.5 reverse stock split which was consummated for historical Diffusion shares in connection with the Merger. In addition, upon consummation of the Merger, all historical EIP shares were adjusted using an exchange ratio of 0.1151. All information in the accompanying consolidated financial statements and notes thereto regarding share amounts of common stock, price per share of common stock and the conversion factor for preferred stock into common stock has been adjusted to reflect the application of the reverse stock split and the exchange ratio on a retroactive basis.

All shares of EIP common stock outstanding immediately prior to the Effective Time, after giving effect to the conversion of EIP preferred stock and the Convertible Notes (and excluding shares held as treasury stock by EIP, shares held or owned by the Company and any dissenting shares), converted into the right to receive, in the aggregate, 4,314,033 shares of the Company's common stock and prefunded warrants to purchase 495,995 shares of common stock, based on an exchange ratio of 0.1151.

2. Liquidity and Capital Resources

The Company has generated negative cash flows from operations and, as of December 31, 2023, had an accumulated deficit of approximately $54.4 million. In January 2023, the Company was awarded a $21.0 million grant from the NIA to support its ongoing RewinD-LB Trial, which is expected to be received over a three-year period. In July 2023, the Company sold common stock for proceeds of $0.8 million. In addition, the Company received $12.7 million in cash and cash equivalents through the reverse recapitalization. The Company expects to continue to generate operating losses for the foreseeable future. The Company's future viability is dependent on its ability to raise additional capital to finance its operations and pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. These conditions cause substantial doubt regarding the Company's ability to continue as a going concern.

The Company will continue to require additional financing to advance 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 expects that its existing cash and cash equivalents as of December 31, 2023, along with the remaining funds expected to be received from the NIA Grant, will not be sufficient to enable it to fund its operating expenses and capital expenditure requirements, and continue as a going concern for at least twelve months following the issuance of these consolidated financial statements. The Company will continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, grants, 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. Without additional funding, the Company would be forced to delay, reduce or eliminate its research and development programs. Accordingly, since the financing discussed below has not been completed, substantial doubt exists about the Company's ability to continue as a going concern within one year after the date these financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On March 28, 2024, the Company entered into a securities purchase agreement with certain purchasers named therein related to 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 for the 2024 Private Placement are expected to be approximately $50 million, before deducting offering fees and expenses, and up to an additional approximately $99.4 million in gross proceeds if the Series A Warrants are fully exercised for cash. The 2024 Private Placement is expected to close on or about April 1, 2024, subject to customary closing conditions. The consolidated financial statements do not reflect and do not include any adjustments for the Company's expected receipt of proceeds from the 2024 Private Placement.

3. Summary of Significant Accounting Policies

Basis of presentation

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

Consolidation

The consolidated 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 consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, grant revenue, expenses, and related disclosures. On an ongoing basis, the Company's management evaluates its estimates, including estimates related to money market accounts, clinical trial accruals, stock-based compensation expense, grant revenue, Convertible Notes, and expenses during the reporting 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 concentrations of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalent balances with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance-sheet risk of loss. The Company has not experienced any losses in such accounts.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value. There are no unrealized gains or losses on the money market funds for the years ended December 31, 2023 and 2022.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, accounts payable, previously outstanding Convertible Notes and accrued liabilities. The Company's cash and cash equivalents, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. The Company determined the fair value of the Convertible Notes as described in Note 9. In connection with the consummation of the Merger (Note 4) on August 16, 2023, the Convertible Notes were converted into EIP Common Stock which was subsequently converted into the right to exchange such shares of EIP Common Stock for shares of the Company's common stock.

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

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

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

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

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

	December 31, 2023		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents (money market accounts)	$ 7,792,846	$ -	$ -
Total assets measured at fair value	$ 7,792,846	$ -	$ -

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

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

	Year Ended	
	December 31, 2023	December 31, 2022
Beginning balance	$ 12,414,000	$ 10,025,000
Fair value adjustment	(5,424,251)	2,389,000
Reclassification to additional paid in capital upon conversion	(6,989,749)	-
Ending balance	$ -	$ 12,414,000

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs (Note 9). The Company's Convertible Notes are classified within Level 3 of the fair value hierarchy because the fair value measurement is based, in part, on significant inputs not observed in the market.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2023 or 2022.

The fair value of the 2020 Notes and the 2021 Notes, and collectively the Convertible Notes (Note 9) as of December 31, 2022 were estimated as the combination of a zero-coupon bond and a call option. The combined values for each of the 2020 Notes and the 2021 Notes as of December 31, 2022 were then weighted by the probability of completing a financing or reverse merger. This approach resulted in the classification of the 2020 Notes and the 2021 Notes as of December 31, 2022 as Level 3 of the fair value hierarchy. The assumptions utilized to value the 2020 Notes and the 2021 Notes as of December 31, 2022 were an estimated term of 0.94 years, volatility of 80.0% and a market yield of 55.2%. The measurement of fair value incorporates expected future cash flows associated with interest payments; as such, there is no separate accrual for interest accrued but not yet paid.

Leases

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

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

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

Research and Development

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

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

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 consolidated statements of operations.

Stock-based Compensation

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

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

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

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

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

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

Grant Revenue Recognition

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

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

Income Taxes

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

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

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

The Company recognizes interest and penalties, if any, related to unrecognized tax benefits on the interest expense line and other expense line, respectively, in the accompanying statements of operations. Accrued interest and penalties are included on the related liability lines in the consolidated balance sheets.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period (and potential shares of common stock that are exercisable for little or no consideration). Diluted loss 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. The pre-funded warrants to purchase common stock issued in connection with the Merger are included in the calculation of basic and diluted net loss per share as the exercise price of $0.001 per share is non-substantive and is virtually assured. The pre-funded warrants are more fully described in Note 11.

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

	December 31,	
	2023	**2022**
Preferred Series A-1	-	1,960,600
Preferred Series A-2	-	335,711
Preferred Series B	-	1,034,890
Warrants	598,457	43,618
Stock options	349,384	114,516
Total	947,841	3,489,335

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 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 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 the Company beginning in the year ended December 31, 2025, with early adoption permitted. 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 No. 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. 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 as discussed in Note 1. For financial reporting purposes, EIP was determined to be the accounting acquirer based upon the terms of the Merger and other factors, including: (i) EIP securityholders immediately prior to the Merger owning approximately 76% of the Company immediately following the Merger, (ii) EIP appointing the majority (five of seven) of the Company's Board 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 statements 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 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	(1,223,871)
Total net assets assumed	11,887,757
Minus: Transaction costs	(1,548,643)
Total net assets assumed minus transaction costs	$ 10,339,114

5. Significant Agreements and Contracts

Vertex Option and License Agreement

In August 2012, the Company entered the 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, 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 years ended December 31, 2023 and 2022.

National Institute of Aging Grant

In January 2023, the Company was awarded a $21.0 million grant from the NIA to support a Phase 2b study of neflamapimod in dementia with Lewy bodies. The grant monies are expected to be received over a period of three years including $6.7 million in 2023, $8.1 million in 2024 and $6.2 million in 2025.

The total revenue recognized from the NIA Grant was $7.1 million year ended December 31, 2023. As of December 31, 2023, total cash funding of $6.2 million has been received from the NIA Grant, resulting in approximately $15.8 million in funding remaining. In addition, $0.9 million has been recorded as a receivable in the consolidated balance sheet at December 31, 2023, which was received subsequent to December 31, 2023.

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 current NIA policy as a result of the U.S. government currently being funded on the basis of a continuing resolution (the "Continuing Resolution").

6. Prepaid Expenses

Prepaid expenses consisted of the following:

	December 31,	
	2023	2022
Prepaid clinical expenses	$ 711,362	$ -
Insurance	436,859	9,937
Rent	-	2,455
Prepaid professional services	37,917	-
Other	70,363	51,735
Total	$ 1,256,501	$ 64,127

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2023	2022
Employee compensation costs	$ 1,026,054	$ 364,070
Clinical development costs	389,045	23,185
Professional fees	309,062	206,675
State franchise and excise tax	120,456	-
Other	88,659	50,322
Total	$ 1,933,276	$ 644,252

8. Line of Credit

The Company established a line of credit with a lender during the year ended December 31, 2020 in the amount of $2.5 million with a variable interest rate of 1.75% over the 30-day LIBOR (7.22% and 6.08% at December 31, 2023 and December 31, 2022, respectively). The line is secured by the personal assets of the Company's Chief Executive Officer and the former Chair of the Board.

No drawdowns were made, and no costs incurred related to the line of credit during the year ended December 31, 2023 or 2022. The line of credit was terminated on February 14, 2024.

9. Convertible Notes

In December 2020, EIP issued the 2020 Notes to predominantly related party investors for proceeds of $5.1 million. In December 2021, EIP issued the 2021 Notes to predominantly related party investors for proceeds of $6.0 million. Upon issuance, the Company elected the fair value option for the Convertible Notes in accordance with ASC 825, "Financial Instruments," pursuant to which the entire instrument, including interest expense, is measured at fair value with the initial change in fair value deemed to be a capital contribution and any subsequent changes in fair value being recorded to other income (expense) on the consolidated statement of operations. The fair value adjustments recognized in other income (expense) were $5.4million and $(2.4)million for the years ended December 31, 2023 and 2022, respectively.

In April 2022, the Company entered into the 2022 Notes Amendment with the noteholders for the 2020 Notes (the "Amendment"). In accordance with the Amendment, the maturity of the 2020 Notes was extended from June 2022 to December 2023, the interest rate was modified so interest accrued at 5% through the original maturity of June 2022 and at 0% thereafter, the conversion discount was increased from 20% to 30%, and a conversion price limit of $3.00 was established, as discussed further below. Expenses associated with the amendment were *de minimis*.

The Company concluded the 2022 Notes Amendment qualified as a troubled debt restructuring, in accordance with FASB ASC 470, Debt, as the noteholders for the 2020 Notes, for economic reasons related to the Company's financial difficulties, granted concessions to the Company. The Company concluded no gain or loss, and no adjustment to, or reclassification of, the carrying value of the 2020 Notes were considered necessary as a result of the 2022 Notes Amendment. In addition, the Company concluded there was no other financial statement impact as a result of the 2022 Notes Amendment, as any prospective change would be related to interest and, as a result of the amendment, the interest rate decreased to 0% following the original maturity of June 2022.

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

The 2023 Notes Amendment qualified as a modification in accordance with FASB ASC 470 *Debt*, since there were no concessions granted and no substantive change to the fair value of the conversion option before and after the 2023 Notes Amendment. There was no financial statement impact as a result of the 2023 Notes Amendment other than the change in fair value of the Convertible Notes during the year ended December 31, 2023 and debt issuance costs of approximately $50,000 that was recorded to general and administrative expenses in the statements of operations.

As a result of the Merger (Note 4), pursuant to the terms thereof, the Convertible Notes converted into shares of EIP Common Stock which were subsequently converted into the right to exchange such shares for 897,272 shares of the Company's common stock and, in certain cases, pre-funded warrants to purchase the Company's common stock. Accordingly, the Convertible Notes were adjusted to fair value prior to conversion by multiplying the trading price of the Company's common stock at the date of the Effective Time and the 795,905 common shares and 101,367 pre-funded warrants issued upon conversion. The Company recorded a gain on the fair value adjustment of the Convertible Notes of $5.4 million for year ended December 31, 2023 and recorded $7.0 million to additional paid in capital for the issuance of common stock upon settlement of the Convertible Notes.

10. Commitments and Contingencies

Operating Leases

The Company has a short-term agreement to utilize membership-based co-working space in Charlottesville, Virginia and a short-term lease for office space in Boston, Massachusetts. Rent expense was approximately $34,000 and $45,000 for the years ended December 31, 2023 and 2022, respectively.

Research and Development Arrangements

In the course of normal business operations, the Company would enter into agreements with universities and CROs to assist in the performance of research and development activities and contract manufacturers to assist with chemistry, manufacturing, and controls related expenses. Expenditures to CROs represented a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

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 *de minimis* amounts for the years ended December 31, 2023 and 2022.

Legal Proceedings

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, the former Chief Executive Officer of the Company's legal predecessor under the caption Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys' fees and costs. On December 30, 2014, the Company filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to the Company's petition to compel arbitration and a motion to stay the action. After a related hearing on April 14, 2015, the court granted the Company's petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. On November 19, 2018 at an Order to Show Cause Re Dismissal Hearing, the court found sufficient grounds not to dismiss the case and an arbitration hearing was scheduled, originally for November 2020 but later postponed due to the COVID-19 pandemic and related restrictions on gatherings in the State of California. In addition, following the November 2018 hearing, an automatic stay was placed on the arbitration in connection with the plaintiff filing for personal bankruptcy protection. On October 22, 2021, following a determination by the bankruptcy trustee not to pursue the claims and release them back to the plaintiff, the parties entered into a stipulation to abandon arbitration and return the matter to state court. A case management conference was held on February 23, 2022 at which an initial trial date of May 24, 2023 was set, and the parties have agreed to stipulate to mediation in advance of the trial. On October 20, 2022, the parties filed a joint stipulation to continue the trial and certain deadlines related to the mediation in order to allow plaintiff's counsel to continue to seek treatment for an ongoing medical issue. On November 1, 2022, based on the parties joint stipulation, the court entered an order continuing the trial date to October 25, 2023, 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.

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

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

On August 16, 2023 in connection with the closing of the Merger, the following is reflected on the consolidated financial statements of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2023: (i) the issuance of 795,905 shares of common stock and 101,367 pre-funded warrants upon the settlement of the Convertible Notes, (ii) the conversion of 3,331,201 shares of convertible preferred stock into 2,936,566 shares of common stock and 394,628 prefunded warrants, and (iii) the issuance of 1,360,244 shares of common stock to Diffusion stockholders as consideration for the Merger.

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

Warrants

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

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

Upon completion of the Merger, the Convertible Notes and outstanding shares of EIP preferred stock converted into shares of EIP Common Stock which were subsequently converted into the right to exchange such shares for shares of the Company's common stock or, in certain cases, pre-funded warrants to purchase the Company's common stock. All of the warrants are equity-classified because they are indexed to the Company's own shares and meet the criteria to be classified as an equity instrument.

The Company is party to the 2022 Sales Agreement with BTIG. The 2022 Sales Agreement is an "at-the-market" sales agreement pursuant to which the Company may, 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. As of the date of this Annual Report, however, the Company has not sold any shares pursuant to the 2022 Sales Agreement.

12. Stock-Based Compensation

2015 Equity Plan

The 2015 Equity Plan provides for increases to the number of shares reserved for issuance thereunder each January 1 equal to 4.0% of the total shares of the Company's common stock outstanding as of the immediately preceding December 31, unless a lesser amount is stipulated by the Compensation Committee of the Company's Board of Directors. As of December 31, 2023, there were 12,580 shares available for future issuance under the 2015 Equity Plan. On January 1, 2024, the number of shares available for future issuance under the 2015 Equity Plan increased by 226,981.

2018 Employee, Director and Consultant Equity Incentive Plan

On March 28, 2018, EIP adopted the 2018 Plan, which was assumed by the Company pursuant to and in accordance with the terms of the Merger Agreement. Under the 2018 Plan, the Company may issue incentive stock options, non-qualified stock options, stock grants, and other stock-based awards to employees, directors, and consultants, as specified in the 2018 Plan and subject to applicable SEC and Nasdaq rules and regulations. The Board of Directors has the authority to determine to whom options or stock will be granted, the number of shares, the term, and the exercise price. Options granted under the 2018 Plan have a term of up to ten years and generally vest over a four-year period with 25% of the options vesting after one-year of service and the remainder vesting monthly thereafter. As of December 31, 2023, 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:

	Year Ended December 31,	
	2023	2022
Research and development	$ 143,685	$ 174,710
General and administrative	263,947	159,125
Total stock-based compensation expense	$ 407,632	$ 333,835

The following table summarizes the activity related to all stock option grants for the year ended December 31, 2023:

	Number of Options	Weighted average exercise price per share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at January 1, 2023	114,516	$ 25.98	6.72	
Options assumed in the merger	52,574	$ 313.67		
Granted	198,600	$ 5.95		
Cancelled	(15,957)	$ 180.80		
Exercised	(359)	$ 5.33		
Outstanding at December 31, 2023	349,374	$ 51.15	8.12	$ 358,340
Exercisable at December 31, 2023	157,301	$ 103.67	6.35	$ 39,820

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:

	December 31,	
	2023	2022
Expected term (in years)	5.75	6.00
Risk-free interest rate	3.9% - 4.5%	1.9%
Expected volatility	81.7% - 83.3%	80.3%
Dividend yield	0.0%	0.0%

During the year ended December 31, 2023, 359 shares underlying options were exercised, of which 193 were withheld as consideration for the exercise price of such shares pursuant to the cashless exercise provision of the related option award agreement. No options were exercised during the year ended December 31, 2022. At December 31, 2023, there was $1.1 million of unrecognized compensation expense that will be recognized over a weighted-average period of 2.1 years.

Contributed Capital in lieu of Executive Compensation

In 2022, the former Chair of the Board and the Chief Executive Officer offered to forego, without repayment, certain compensation to ensure the Company had enough resources to maintain operations until the financial funding was completed. The amount of $0.1 million for the year ended December 31, 2022, which is recorded as contributed capital in lieu of executive compensation in additional paid-in capital, will not be paid in cash, debt or equity in the future. No such event occurred during the year ended December 31, 2023.

13. Income Taxes

A reconciliation of income tax benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements as of December 31, 2023 and 2022:

Rate reconciliation:	**2023**	**2022**
Federal tax benefit at statutory rate	21.0%	21.0%
State tax, net of federal benefit	6.3%	8.0%
Change in convertible debt	52.8%	-8.6%
Research & Development credit	17.1%	1.2%
Change in valuation allowance	-95.9%	-15.8%
Share-based compensation	-1.0%	0.0%
Other	-0.3%	-5.8%
Total provision	0.0%	0.0%

Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which differences are expected to reverse.

Significant components of the Company's deferred tax assets for federal income taxes as of December 31, 2023 and December 31, 2022 consisted of the following:

	2023	**2022**
Deferred tax assets:		
Net operating loss	$ 10,495,881	$ 10,977,455
Research and development credits	708,443	354,283
Capitalized research expenditures	2,271,853	259,749
Stock-based compensation	567,473	514,654
Reserves and accruals	-	105,399
Intangibles	223,548	262,872
Gross deferred tax assets	14,267,198	12,474,412
Less valuation allowance	(14,100,543)	(12,474,412)
Total deferred tax assets	166,655	-
Deferred tax liabilities:		
Prepaids	$ (166,655)	$ -
Gross deferred tax liabilities	(166,655)	-
Deferred tax assets, net	$ -	$ -

The Company does not have unrecognized tax benefits as of December 31, 2023 or December 31, 2022. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Evaluating the need for a valuation allowance for deferred tax assets often requires judgment and analysis of all the positive and negative evidence available, including cumulative losses in recent years and projected future taxable income, to determine whether all or some portion of the deferred tax assets will not be realized. As of December 31, 2023, the Company has utilized a full valuation allowance to offset the net deferred tax assets as the Company believes it is not more likely than not that the net deferred tax assets will be fully realizable. The valuation allowance increased by $1.6 million during the year ended December 31, 2023.

As of December 31, 2023, the Company had NOL carryforwards of approximately $38.9 million and $37.0 million for federal and state tax purposes, respectively. Federal NOL carryforwards will not expire and state NOL carryforwards will begin to expire in 2038, if not utilized. The TCJA enacted on December 22, 2017 limits a taxpayer's ability to utilize NOL deduction in a year to 80% taxable income for federal net operating losses arising in tax years beginning after 2017, however, federal NOLs post 2017, are now indefinite lived.

As of December 31, 2023, the Company also had federal and state research credit carryforwards of $0.6 million and $0.1 million, respectively. The federal and state research credits will begin to expire in 2038 and 2034, respectively.

Generally, utilization of the NOL carryforwards and credits may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Code, which provides for limitations on NOL carryforwards and certain built-in losses following ownership changes, and Section 383 of the Code, which provides for special limitations on certain excess credits, as well as similar state provisions. Accordingly, the Company's ability to utilize NOL carryforwards may be limited as the result of such an "ownership change." A formal Section 382 study was performed through December 31, 2023 which resulted concluded there have been no historical section 382 ownership changes, thus the NOL carryforwards are not be subject to an annual limitation. With respect to Diffusion, the Company deems the historical Diffusion tax attributes (NOLs/Credits) are unusable due to the IRC Section 382 limitation. ASC 740-10-25 states that a "write off might be appropriate if there is only a remote likelihood that the entity will utilize the carryforward (i.e. NOL), it is acceptable for the entity to write off the deferred tax assets against the valuation allowance, thereby eliminating the need to disclose the gross amounts. As such, the Company has written off these attributes.

The Company files federal and state income tax returns in jurisdictions with varying statutes of limitations. Due to its NOL carryforwards, the Company's income tax returns generally remain subject to examination by federal and state tax authorities. The Company is currently not subject to any income tax audits by federal or state taxing authorities. The statute of limitations for tax liabilities for all years remains open.

The Company uses the "more likely than not" criterion for recognizing the income tax benefit of uncertain income tax positions and establishing measurement criteria for income tax benefits. The Company has evaluated the impact of these positions and believes that its income tax filing positions and deductions will be sustained upon examination. Accordingly, no reserves for uncertain income tax positions or related accruals for interest and penalties have been recorded as of December 31, 2023 and 2022.

14. Subsequent Events

2024 Private Placement

On March 28, 2024, the Company entered into a securities purchase agreement with certain purchasers named therein related to 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 2024 Private Placement is expected to close on or about April 1, 2024, subject to customary closing conditions. The aggregate upfront gross proceeds from the 2024 Private Placement are expected to be approximately $50 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.

Pre-Funded Warrant Amendment and Exercise

On February 26, 2024, following the effectiveness of an amendment eliminating certain beneficial ownership limitations set forth therein, the Company's previously outstanding pre-funded warrant was exercised in full by the holder thereof pursuant to the cashless exercise provision in Section 2(c) of the pre-funded warrant. 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.

5,064,570 Shares of Common Stock

CERVODMED INC.

PROSPECTUS

, 2024

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses payable in connection with the sale and distribution of the securities being registered. All amounts are estimate except the Securities and Exchange Commission registration fee.

SEC registration fee	$	17,908
Printing and engraving expenses		2,500
Legal fees and expenses		175,000
Accountants' fees and expenses		25,000
Miscellaneous expenses		5,000
Total	$	225,408

ITEM 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the DGCL, the Company's certificate of incorporation, as amended (the "Charter"), eliminates the liability of directors to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent otherwise required by the DGCL, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

Section 145 of the DGCL permits indemnification of officers and directors under certain circumstances in connection with liabilities (including reimbursement for expenses incurred) arising under the Securities Act. The Charter provides that the Company will indemnify any person who is or was made a party to any proceeding by reason of the fact that such person is or was a director or officer of the Company against expenses, judgments, fines, penalties, and amounts paid in settlement incurred in connection therewith to the fullest extent authorized by the DGCL. The Company's bylaws, as amended (the "Bylaws"), provide for a similar indemnity to directors and officers of the Company to the fullest extent authorized by the DGCL.

The Company's Bylaws authorize the Company's board of directors to enter into indemnification contracts with each of its officers and directors. The Company has entered into indemnification contracts with each of its directors and executive officers. The indemnification contracts provide for the indemnification of directors and officers against all expenses, liability, and loss actually reasonably incurred to the fullest extent permitted by the Company's Charter, Bylaws, and applicable law.

The Company's Bylaws also authorize the Company to maintain insurance to protect any director or officer against any expense, liability, or loss, whether or not the Company would have the power to indemnify such person against such expense, liability, or loss under the DGCL.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, the Company has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

ITEM 15. Recent Sales of Unregistered Securities

The following information is furnished with regard to all securities issued by the registrant within the last three years that were not registered under the Securities Act of 1933, as amended. Unless otherwise indicated below, the issuance of such shares was deemed exempt from registration requirements of the Securities Act, of 1933, as amended, as such sales were exempt from registration under Section 4(2) of Securities Act of 1933, as amended and/or Rule 506 of Regulation D promulgated thereunder.

On March 28, 2024, we entered into the Purchase Agreement with the Purchasers for the private placement of an aggregate of 2,532,285 Units, each Unit comprised of (i) (A) one share of Common Stock or (B) one Pre-Funded Warrant, and, in each case, (ii) one Series A Warrant. A Unit comprised of one share of Common Stock and one Series A Warrant had a purchase price of $19.745 and a Unit comprised of one Pre-Funded Warrant and one Series A Warrant had a purchase price of $19.744. The 2024 Private Placement closed on April 1, 2024.

The gross proceeds for the 2024 Private Placement were approximately $50.0 million, before deducting offering fees and expenses, and up to an additional $99.4 million in gross proceeds if the Series A Warrants are fully exercised for cash.

Each Pre-Funded Warrant has an exercise price of $0.001 per Warrant Share, is immediately exercisable on the date of issuance and will not expire. The Series A Warrants have an exercise price equal to $39.24 per Warrant Share, are exercisable immediately and will expire at the earlier of (i) April 1, 2027 or (ii) 180 days after the date that we make a public announcement of positive top-line data from the our RewinD-LB Trial evaluating neflamapimod for treatment of patients with DLB.

ITEM 16. Exhibits and Financial Statement Schedules

(a) The Exhibit Index is incorporated herein by reference.

See the Exhibit Index attached to this registration statement, which is incorporated herein by reference.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

INDEX TO EXHIBITS

No.	Description	Method of Filing
2.1Δ	Agreement and Plan of Merger, dated as of March 30, 2023, by and among Diffusion Pharmaceuticals Inc., EIP Pharma, Inc. and Dawn Merger Sub Inc.	Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on March 30, 2023.
3.1	Certificate of Incorporation of CervoMed Inc., as amended	Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed on March 24, 2023.
3.2	Certificate of Amendment, dated August 16, 2023, to the Certificate of Incorporation, as amended, of CervoMed Inc. (Reverse Stock Split)	Incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on August 17, 2023.
3.3	Certificate of Amendment, dated August 16, 2023, to the Certificate of Incorporation, as amended, of CervoMed Inc. (Name Change)	Incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K filed on August 17, 2023.
3.4	Bylaws of CervoMed Inc., as amended	Incorporated by reference to Exhibit 3.5 to the Company's Current Report on Form 8-K filed on August 17, 2023.
4.1	Form of May 2019 Investor Warrant	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 28, 2019.
4.2	Form of May 2019 Placement Agent Warrant	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 28, 2019.
4.3	Form of November 2019 Series I Investor Warrant	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 13, 2019.
4.4	Form of November 2019 Series II Investor Warrant	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 13, 2019.
4.5	Form of December 2019 Investor Warrant	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 13, 2019.
4.6	Form of December 2019 Placement Agent Warrant	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on December 13, 2019.

4.7	Form of May 2020 Placement Agent Warrant (In Respect of Exercise Transaction)	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 8, 2020.
4.8	Form of May 2020 Placement Agent Warrant (In Respect of Offering Transaction)	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 20, 2020.
4.9	Form of February 2021 Underwriter Warrant	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 18, 2021.
4.10	Form of 2023 Pre-Funded Investor Warrant	Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on August 17, 2023.
4.11	Amendment to Pre-Funded Warrant, dated as of February 26, 2024, by and between CervoMed Inc. and the Joshua S. Boger 2021 Trust DTD 12/09/2021	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on February 28, 2024.
4.12	Form of EIP 2018 Investor Warrant	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on August 17, 2023.
4.13	Form of EIP 2018 Investor Warrant (AI EIPP Holdings LLC)	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 17, 2023.
4.14	Form of Series A Warrant issued in connection with the 2024 Private Placement	Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 28, 2024
4.15	Form of Pre-Funded Warrant issued in connection with the 2024 Private Placement	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 28, 2024
4.16	Specimen Stock Certificate	Incorporated by reference to Exhibit 4.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.
4.17	Description of Securities of CervoMed Inc.	Incorporated by reference to Exhibit 4.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.
5.1	Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.	Filed herewith.
10.1#	Amended & Restated Employment Agreement, dated as of February 1, 2024, by and between John Alam, M.D. and CervoMed Inc.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 2, 2024.
10.2#	Amended & Restated Employment Agreement, dated as of February 1, 2024, by and between Robert J. Cobuzzi, Jr., Ph.D. and CervoMed Inc.	Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 2, 2024.
10.3#	Employment Agreement, dated as of November 15, 2023, by and between J. William Tanner, Ph.D. and CervoMed Inc.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 17, 2023.

10.4#	Employment Agreement, dated as of February 1, 2024, by and between Kelly Blackburn and CervoMed Inc.	Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on February 2, 2024.
10.5#	Employment Agreement, dated as of September 23, 2020, by and between William Elder and CervoMed Inc.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 25, 2020.
10.6#	Amendment to Employment Agreement, dated March 29, 2023, by and between CervoMed Inc. and William Elder	Incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on March 30, 2023.
10.7#	CervoMed Inc. 2015 Equity Incentive Plan	Incorporated by reference to Appendix C to the Company's definitive proxy statement on Schedule 14A filed on June 10, 2016.
10.8#	Amendment No. 1 to CervoMed Inc. 2015 Equity Incentive Plan	Incorporated by reference to Appendix B to the Company's definitive proxy statement on Schedule 14A filed on June 10, 2016.
10.9#	EIP Pharma, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan	Incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-4/A filed on July 12, 2023.
10.10#	Form of Stock Option Award Agreement under 2015 Equity Incentive Plan	Incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.
10.11#	Form of Stock Option Award Agreement under 2018 Employee, Director and Consultant Equity Incentive Plan	Incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.
10.12#	Form of Indemnification Agreement between CervoMed Inc. and each of its directors and officers	Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.
10.13*	Option and License Agreement, dated as of August 27, 2012, by and between EIP Pharma LLC and Vertex Pharmaceuticals Incorporated	Incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-4/A filed on July 12, 2023.
10.14*	Amendment No.1, dated as of April 8, 2014, to Option and License Agreement, dated August 27, 2012, by and between EIP Pharma LLC and Vertex Pharmaceuticals Incorporated	Incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-4/A filed on July 12, 2023.
10.15*	Amendment No.2, dated as of November 17, 2015, to Option and License Agreement, dated August 27, 2012, as amended April 18, 2014, by and between EIP Pharma LLC and Vertex Pharmaceuticals Incorporated	Incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-4/A filed on July 12, 2023.
10.16	At-The-Market Sales Agreement, dated as of July 22, 2022, by and between CervoMed Inc. and BTIG, LLC	Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on July 22, 2022.
10.17	Form of EIP Subscription Agreement, dated as of July 10, 2023	Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 13, 2023.
10.18	Form of Lock-up Agreement, dated as of March 30, 2023, related to Merger Agreement	Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 30, 2023.

10.19	Securities Purchase Agreement, dated March 28, 2024, by and between CervoMed Inc. and each of the purchasers party thereto, related to the 2024 Private Placement	Filed herewith.
21.1	Subsidiaries of CervoMed Inc.	Incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.
23.1	Consent of RSM US LLP, independent registered public accounting firm	Filed herewith.
23.2	Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.	Contained in Exhibit 5.1
24.1	Power of Attorney	Included on the signature page hereto.
101	The following materials for the year ended December 31, 2023, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements	Filed herewith.
104	Cover Page Interactive Data File	Embedded within the Inline XBRL document and contained in Exhibit 101.
107	Filing Fee Exhibit	Filed herewith.

#	Indicates a management contract or compensatory plan or arrangement.
Δ	Schedules and exhibits have been omitted from this filing pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish on a supplemental basis a copy of any omitted schedule or exhibit to the SEC upon its request; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule or exhibit so furnished.
*	Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

ITEM 17. Undertakings

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933,

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement, and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document; incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(6) The undersigned registrant hereby undertakes that: (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h)under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective. (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Boston, Massachusetts, on this 10th day of May, 2024.

CERVOMED INC.

By: /s/ John Alam, M.D.
John Alam, M.D.
President and Chief Executive Officer

We, the undersigned, hereby severally constitute and appoint each of John Alam, M.D. and William Elder, each in their individual capacity, our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to execute any and all amendments (including post-effective amendments) to this registration statement, to sign any registration statement filed pursuant to Rule 462 of the Securities Act of 1933, as amended, and to cause the same to be filed with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and desirable to be done in and about the premises as fully and to all intents and purposes as we might or could do in person, hereby ratifying and confirming all facts and things that said attorney-in-fact and agent, or his substitute may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the date indicated.

Name and Signature	Title(s)	Date
/s/ John Alam, M.D. John Alam, M.D.	President, Chief Executive Officer, and Director, (Principal Executive Officer)	May 10, 2024
/s/ William Elder William Elder	General Counsel & Corporate Secretary (Acting Principal Financial Officer)	May 10, 2024
/s/ Joshua S. Boger, Ph.D. Joshua S. Boger, Ph.D.	Chair of the Board of Directors	May 10, 2024
/s/ Robert J. Cobuzzi, Ph.D. Robert J. Cobuzzi, Ph.D.	Director and Chief Operating Officer	May 10, 2024
/s/ Sylvie Grégoire, PharmD. Sylvie Grégoire, PharmD.	Director	May 10, 2024
/s/ Jane H. Hollingsworth, J.D. Jane H. Hollingsworth, J.D.	Director	May 10, 2024
/s/ Jeff Poulton Jeff Poulton	Director	May 10, 2024
/s/ Marwan Sabbagh, M.D. Marwan Sabbagh, M.D.	Director	May 10, 2024
/s/ Frank Zavrl Frank Zavrl	Director	May 10, 2024

Exhibit 5.1

One Financial Center
Boston, MA 02111
617 542 6000
mintz.com

May 10, 2024

CervoMed Inc.
20 Park Plaza, Suite 424
Boston, MA 02116

Ladies and Gentlemen:

We have acted as counsel to CervoMed Inc., a Delaware corporation (the "Company"), in connection with the issuance of this opinion that relates to a Registration Statement on Form S-1 (the "Registration Statement") filed by the Company with the United States Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement covers the resale, by the selling shareholders listed therein, from time to time pursuant to Rule 415 under the Securities Act as set forth in the Registration Statement, of shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), which consist of (i) 2,083,262 shares of Common Stock (the "PIPE Shares") delivered to the selling shareholders pursuant to the Agreement (as defined below), (ii) 449,023 shares of Common Stock issuable upon the exercise of pre-funded warrants (the "Pre-Funded Warrants") to purchase shares of Common Stock held by a selling stockholder (the "Pre-Funded Warrant Shares"), and (iii) 2,532,285 shares of Common Stock issuable upon the exercise of outstanding Series A warrants (the "Series A Warrants," and collectively with the Pre-Funded Warrants, the "Warrants") to purchase shares of Common Stock held by the selling stockholders (the "Series A Warrant Shares," and together with the Pre-Funded Warrant Shares, the "Warrant Shares") pursuant to the Securities Purchase Agreement by and between the Company and the purchasers identified as parties thereto, dated as of March 28, 2024 (the "Agreement").

In connection with the issuance of this opinion letter, we have examined originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates and receipts of public officials, certificates of officers or other representatives of the Company and others, and such other documents as we have deemed necessary or appropriate as a basis for the opinions stated below. As to any facts relevant to the opinions stated herein that we did not independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and of public officials.

In our examination, we have assumed (a) the genuineness of all signatures, including endorsements, (b) the legal capacity and competency of all natural persons, (c) the authenticity of all documents submitted to us as originals, (d) the conformity to original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies, and (e) the accuracy, completeness and authenticity of certificates of public officials.

Based upon the foregoing and subject to the qualifications and assumptions stated herein, we are of the opinion that:

1. The PIPE Shares have been duly authorized by all requisite corporate action on the part of the Company under the General Corporation Law of the State of Delaware (the "DGCL") and are validly issued, fully paid, and non-assessable.

2. The Warrant Shares have been duly authorized by all requisite corporate action on the part of the Company under the DGCL and, when the Warrant Shares are delivered and paid for in accordance with the terms of the Warrants and when evidence of the issuance thereof is duly recorded in the Company's books and records, the Warrant Shares will be validly issued, fully paid, and non-assessable.

Our opinion is expressly limited to the matters set forth above, and we render no opinion, whether by implication or otherwise, as to any other matters relating to the Company, the PIPE Shares, the Warrants, the Warrant Shares, the Agreement or any other agreements or transactions that may be related thereto or contemplated thereby. We are expressing no opinion as to any obligations that parties other than the Company may have under or in respect of the PIPE Shares or the Warrant Shares, or as to the effect that their performance of such obligations may have upon any of the matters referred to above. No opinion may be implied or inferred beyond the opinion expressly stated above.

Our opinion is limited to the DGCL and we express no opinion with respect to the laws of any other jurisdiction. No opinion is expressed herein with respect to the qualification of the PIPE Shares, the Warrants or the Warrant Shares under the securities or blue sky laws of any state or any foreign jurisdiction.

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein. We understand that you wish to file this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K promulgated under the Securities Act and to reference the firm's name under the caption "Legal Matters" in the Prospectus, and we hereby consent thereto. In giving this consent, we do not admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Mintz Levin Cohn Ferris Glovsky and Popeo, PC

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

CERVOMED INC.

SECURITIES PURCHASE AGREEMENT

THIS SECURITIES PURCHASE AGREEMENT (the "***Agreement***") is made as of March 28, 2024 (the "***Effective Date***"), by and between **CERVOMED INC.**, a Delaware corporation (the "***Company***"), and each of the purchasers whose names are set forth on Schedule A hereto (each, a "***Purchaser***" and, collectively, the "***Purchasers***").

WHEREAS, the Purchasers desire to purchase, severally and not jointly, and the Company has agreed to sell and issue to the Purchasers, upon the terms and subject to the conditions set forth in this Agreement, an aggregate of $50 million of units (the "***Units***") set forth opposite the name of such Purchaser on Schedule A hereto, each Unit comprised of (i) (A) one share of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), or (B) one pre-funded warrant, in the form attached hereto as Exhibit A, to purchase shares of Common Stock (each, a "***Pre-Funded Warrant***"), and in each case, (ii) one warrant, in the form attached hereto as Exhibit B, to purchase shares of Common Stock or a pre-funded warrant to purchase Common Stock (each, a "***Series A Warrant***").

WHEREAS, in connection with the issuance and sale of the Securities to the Purchasers on the terms and subject to the conditions set forth in this Agreement, the Company has entered into a placement agent agreement (the "***Placement Agent Agreement***") with Morgan Stanley & Co. LLC and Canaccord Genuity LLC (collectively, the "***Placement Agents***").

AGREEMENT

In consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Purchasers hereby agree, severally and not jointly, as follows:

SECTION 1. AUTHORIZATION OF SALE OF SECURITIES.

The Company has authorized the sale and issuance of the Securities to the Purchasers on the terms and subject to the conditions set forth in this Agreement.

SECTION 2. AGREEMENT TO SELL AND PURCHASE THE SECURITIES.

2.1 **Purchase**. At the Closing (as defined below), the Company will issue, sell and deliver to each Purchaser, and such Purchaser will purchase, severally and not jointly, from the Company, that number of Units set forth opposite such Purchaser's name on Schedule A hereto, inclusive of the number of shares of Common Stock and/or Pre-Funded Warrants and the number of Series A Warrants indicated thereon. The purchase price per Unit shall be $19.745 (the "***Purchase Price***"); provided, however, that to the extent Pre-Funded Warrants are purchased, the price of such Unit shall be equal to the Purchase Price minus $0.001. The Pre-Funded Warrants shall have an exercise price equal to $0.001 per Warrant Share. The Series A Warrants shall have an exercise price equal to $39.24 per Warrant Share. For the avoidance of doubt, the election to receive Pre-Funded Warrants is solely at the option of the Purchaser.

2.2 **Definitions**. For purposes of this Agreement, the following terms shall have the following meanings:

(a) "***Affiliate***" means, with respect to any Person, any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, as such terms are used in and construed under Rule 405 under the Securities Act of 1933, as amended (the "***Securities Act***").

(b) "***Business Day***" means a day, other than a Saturday or Sunday, on which banks in New York City are open for the general transaction of business.

(c) "***Common Stock Equivalents***" shall mean any securities of the Company that would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

(d) "***Exempt Filing***" means the filing by the Company with the United States Securities and Exchange Commission (the "***Commission***") on or after the Effective Date of (i) any registration statement on Form S-8 in connection with the offer and sale of securities to be issued pursuant to any equity incentive plan, (ii) a universal "shelf" registration statement on Form S-3 so long as no securities are sold thereunder, and/or (iii) any Registration Statement (as defined below) filed in connection with this Agreement (which, for the avoidance of doubt, includes the Secondary Registration Statement (as defined below)).

(e) "***Exempt Issuance***" means (i) the issuance of shares of Common Stock, restricted stock units, options or other stock awards to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose as of the Effective Date, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company; (ii) the issuance and sale of the Securities to be issued hereunder and securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities; (iii) the issuance of shares of Common Stock in connection with any agreement in effect as of the Effective Date that provides for an "at-the-market" offering within the meaning of Rule 415(a)(4) of the Securities Act; and (iv) the issuance of securities issued pursuant to any licensing, collaboration, acquisition or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a person (or to the equityholders of a person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities (provided, however, that the aggregate number of shares of Common Stock issued pursuant to clause (iv) during the restricted period shall not exceed 10% of the total number of shares of Common Stock issued and outstanding immediately following the Closing).

(f) "***GAAP***" means United States generally accepted accounting principles.

(g) "***Governmental Entity***" means any national, federal, state, county, municipal, local or foreign government, or other political subdivision thereof or any other governmental, administrative, judicial, arbitral, legislative, executive, regulatory or self-regulatory authority (including the Trading Market), instrumentality, agency, commission or body and any entity exercising executive, legislative, judicial, regulatory, taxing or administrative functions of or pertaining to government.

(h) "***Knowledge of the Company***" means, with respect to the Company, such statement is based upon the actual knowledge, or knowledge that would have been acquired after reasonable inquiry, of the executive officers of the Company having responsibility for the matter or matters that are the subject of the statement.

(i) "***Law***" means any federal, state, local or foreign law (including common law), statute, code, ordinance, rule, regulation, order, judgment, writ, stipulation, award, injunction, decree, arbitration award or finding or any other legally enforceable requirement.

(j) "***Material Adverse Effect***" shall mean any change, event, development, condition, occurrence or effect that, individually or in the aggregate with all other changes, events, developments, conditions, occurrences or effects (i) is, or would reasonably be expected to be, materially adverse to the business, financial condition, assets, liabilities or results of operations of the Company and its subsidiaries considered as one enterprise, or (ii) materially impairs the ability of the Company to comply, or prevents the Company from complying, with its material obligations with respect to the Closing or would reasonably be expected to do so, or (iii) is, or would reasonably be expected to be, materially adverse to the validity of the Securities purchased hereunder or the legal authority of the Company to comply in all material respects with the terms of this Agreement; provided, however, that none of the following will be deemed in themselves, either alone or in combination, to constitute, and that none of the following will be taken into account in determining whether there has been or will be, a Material Adverse Effect under subclause (a) of this definition:

A. any change generally affecting the economy, financial markets or political, economic or regulatory conditions in the United States or any other geographic region in which the Company conducts business, if the Company is not disproportionately affected thereby;

B. general financial, debt, banking, capital, credit or securities market conditions, including interest rates or exchange rates, or any changes therein, if the Company is not disproportionately affected thereby;

C. any change that generally affects industries in which the Company conducts business, if the Company is not disproportionately affected thereby;

D. changes in Laws after the date hereof, if the Company is not disproportionately affected thereby;

E. any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or any worsening of such epidemic, pandemic or disease outbreak or any declaration of martial law, quarantine or similar directive, policy or guidance or Law or other action by any Governmental Entity in response thereto,

F. changes in GAAP after the date of this Agreement, if the Company is not disproportionately affected thereby; or

F. any change arising in connection with earthquakes, hostilities, acts of war, acts of God, natural disasters, sabotage or terrorism, military actions or any escalation or material worsening of any such hostilities, acts of war, acts of God, natural disasters, sabotage or terrorism or military actions;

provided, that the underlying cause of any change described in the foregoing clauses (A) through (G) may be deemed to constitute, or be taken into account in determining whether there has been or will be, a Material Adverse Effect under subclause (i) of this definition, except to the extent any such change would otherwise be excepted from this definition in accordance with the foregoing.

(l) "***Person***" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

(m) "***Securities***" means, collectively, the Units, the Shares, the Warrant Shares and the Warrants.

(n) "***Shares***" means the shares of Common Stock included in the Units purchased by the Purchasers pursuant to the terms and conditions hereof.

(o) "***Short Sales***" means any short sales including, without limitation, (i) all "short sales" as defined in Rule 200 promulgated under Regulation SHO under the Exchange Act, whether or not against the box, and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, swaps, "put equivalent positions" (as defined in Rule 16a-1(h) under the Exchange Act) and similar arrangements (including on a total return basis), and (ii) sales and other transactions through non-U.S. broker-dealers or non-U.S. regulated brokers (but shall not be deemed to include the location and/or reservation of borrowable shares of Common Stock).

(p) "***Standard Settlement Period***" means the standard settlement period, expressed in a number of Trading Days, for the Principal Trading Market with respect to the Common Stock.

(q) "***subsidiary***" means any individual or entity the Company wholly-owns or controls, or in which the Company, directly or indirectly, owns a majority of the voting stock or similar voting interest, in each case that would be disclosable pursuant to Item 601(b)(21) of Regulation S-K promulgated under the Securities Act.

(r) "***Trading Day***" means a day on which the Trading Market is open for trading.

(s) "***Trading Market***" means the Nasdaq Capital Market.

(t) "***Warrants***" means the Pre-Funded Warrants and Series A Warrants.

(u) "***Warrant Shares***" means the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants and Series A Warrants, including any shares of Common Stock issuable pursuant to the pre-funded warrants issuable pursuant to the Series A Warrants.

(v) "***Variable Rate Transaction***" means a transaction in which the Company issues or sells: (i) any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion, exercise, or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise, or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into any agreement, including, but not limited to, an equity line of credit, whereby the Company may sell securities at a future determined price, but in any case shall exclude any at-the-market offering program for equity securities entered into by the Company.

SECTION 3. CLOSING, CLOSING CONDITIONS AND CLOSING DELIVERIES.

3.1 **Closing**. The closing of the purchase and sale of the Securities pursuant to this Agreement (the "***Closing***") shall occur on April 1, 2024, subject to the satisfaction or waiver of all of the conditions set forth in Section 3.2 and the delivery of all of the closing deliveries set forth in Section 3.3 (such date, the "***Closing Date***"), at the offices of Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C., One Financial Center, Boston, Massachusetts 02111, or at such other time and place as may be agreed to by the Company and the Purchasers.

3.2 **Closing Conditions**.

(a) Mutual Closing Condition. There shall have been no Law enacted, entered, promulgated, enforced or deemed applicable by any Governmental Entity of competent jurisdiction that is in effect and makes illegal or otherwise prohibits or materially delays the consummation of the Closing.

(b) Conditions to Purchaser's Obligations. Each Purchaser's obligation to purchase the Securities at the Closing is subject to the fulfillment, on or before the Closing, of each of the following conditions, unless waived:

i. The Company's representations and warranties in Section 4 shall be true and correct in all material respects at the Closing Date (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects), with the same force and effect as if they had been made on and as of the Closing Date, except to the extent any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects).

ii. The Company shall have performed and complied with in all material respects all agreements and conditions herein required to be performed or complied with by the Company on or before the Closing, or any breach or failure to do so has been cured.

iii. There shall have been no Material Adverse Effect with respect to the Company since the date hereof.

iv. From the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Trading Market, nor shall suspension have been threatened either (A) in writing by the Commission or the Trading Market or (B) by falling below the minimum maintenance requirements of the Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on the Trading Market, nor shall a banking moratorium have been declared by the United States or New York authorities.

v. The Company shall have filed with the Trading Market a Listing of Additional Shares notification form for the listing of the Shares and the applicable Warrant Shares. No objection shall have been raised by the Trading Market with respect to the consummation of the transactions contemplated by this Agreement.

vi. The Company shall have delivered the closing deliverables set forth in Section 3.3 to the Purchasers and Placement Agents.

vii. The Company shall have obtained any and all consents, permits, approvals, registrations and waivers necessary for the consummation of the purchase and sale of the Securities and the consummation of the other transactions contemplated by this Agreement, all of which shall be in full force and effect.

(c) Conditions to the Company's Obligations. The Company's obligation to issue and sell the Securities at the Closing to a Purchaser is subject to the fulfillment, on or before the Closing, of each of the following conditions, unless waived:

i. Such Purchaser's representations and warranties in Section 5 shall be true and correct in all material respects (or, to the extent such representations and warranties are qualified by materiality, in all respects) at the date of the Closing, with the same force and effect as if they had been made on and as of said date, except to the extent any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct in all material respects (or, to the extent such representations and warranties are qualified by materiality, in all respects) as of such earlier date.

ii. Such Purchaser shall have performed and complied with in all material respects all agreements and conditions herein required to be performed or complied with by it on or before the Closing, or any breach or failure to do so has been cured.

3.3 **Closing Deliveries.**

(a) **Payment of the Purchase Price at Closing**. At the Closing, each Purchaser shall deliver, or cause to be delivered, to the Company, an amount equal to such Purchaser's aggregate Purchase Price as set forth on Schedule A hereto by wire transfer of immediately available funds to the Company's account pursuant to wire instructions set forth in Schedule B. Each Purchaser's obligations to pay the Purchase Price shall be several and not joint. If a Purchaser informs the Company (i) that it is an investment company registered under the Investment Company Act of 1940, as amended, (ii) that it is advised by an investment adviser subject to regulation under the Investment Advisers Act of 1940, as amended, or (iii) that its internal compliance policies and procedures so require it, then (1) prior to the delivery by such Purchaser of its Purchase Price, the Company shall deliver evidence of the issuance of the Shares from the Company's transfer agent as described below in Section 3.3(b), and (2) following receipt of such evidence, such Purchaser shall deliver at the Closing its Purchase Price.

(b) **Issuance of the Shares at the Closing**. At the Closing, the Company shall issue, or cause the Company's transfer agent to issue, to each Purchaser in global form through a book-entry account maintained by the Company's transfer agent the number of Shares included in the Units purchased by such Purchaser, as set forth in Schedule A hereto, at the Closing against payment by such Purchaser of the Purchase Price (including providing a copy of the irrevocable instructions delivered by the Company to the Company's transfer agent instructing the transfer agent to issue such Shares to the Purchaser (or its nominee in accordance with such Purchaser's delivery instructions) by crediting such Shares to the Purchaser's account (or the account of its nominee in accordance with such Purchaser's delivery instructions) on the transfer agent's book-entry system on the Closing Date and confirmation from the transfer agent that such Shares were so issued on the date thereof, or if requested by such Purchaser, a copy of the book-entry statement reflecting the issuance of such Shares). Such Shares shall be appropriately legended as set forth in Section 5.11 herein.

(c) **Issuance of the Warrants at the Closing**. At the Closing, the Company will deliver or cause to be delivered to each Purchaser (or such Purchaser's designated custodian per its delivery instructions) a PDF wet-ink copy of the Series A Warrants purchased by the Purchaser, and, if applicable, a PDF wet-ink copy of the Pre-Funded Warrants purchased by such Purchaser (with the original Warrants to be delivered to Purchaser within five (5) Business Days of Closing), registered in such Purchaser's name. Such delivery shall be against payment of the Purchase Price therefor.

(d) **Secretary's Certificate**. At the Closing, each of the Purchasers and Placement Agents shall have received a certificate signed by the Secretary of the Company, in form and substance reasonably satisfactory to the Purchasers and Placement Agents, (i) certifying the resolutions of the Board of Directors of the Company or a duly authorized committee thereof approving this Agreement and all of the transactions contemplated hereunder, (ii) certifying the current versions of the Company's Certificate of Incorporation and Bylaws and (iii) attaching a certificate evidencing the good standing of the Company in Delaware issued by the Secretary of State of Delaware, as of a date within five Business Days of the Closing Date.

(e) **Compliance Certificate**. At the Closing, each of the Purchasers and Placement Agents shall have received a certificate, in form and substance reasonably satisfactory to the Purchasers and the Placement Agents, signed by the President and Chief Executive Officer of the Company certifying to the fulfillment of the conditions set forth in Section 3.2(a) and (b).

(f) **Opinion.** At the Closing, each of the Purchasers shall have received an opinion (the "***Opinion***") of Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C., counsel for the Company, dated as of the Closing Date, in a form reasonably satisfactory to the Purchasers and Placement Agents, and a letter from such counsel to the Placement Agents to the effect that the Placement Agents may rely on each such Opinion to the same extent as if such Opinion or opinions had been addressed to the Placement Agents.

(g) **Lock-up Agreements**. At the Closing, each of the Purchasers and Placement Agents shall have received executed lock-up agreements, dated as of the date hereof, by and among the Company and the directors and executive officers of the Company, all of whom are listed on Schedule C hereto, in the form attached hereto as Exhibit C (the "***D&O Lock-up***"), which lock-up agreement may only be waived by the Company upon receipt of written consent of Morgan Stanley & Co. LLC.

(h) **Investor Representation Letter**. At the Closing, each Purchaser shall have delivered to the Placement Agents an investor representation letter, in the form attached hereto as Exhibit D.

(i) **Other Documents**. At the Closing, each Purchaser shall have delivered to the Company any other documents reasonably requested in order to effect the transactions contemplated by this Agreement.

SECTION 4. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.

Except as disclosed in the SEC Documents (as defined below) prior to the Effective Date and only as and to the extent disclosed therein, the Company hereby represents, warrants and covenants to each of the Purchasers and Placement Agents as follows:

4.1 **Organization and Standing; Subsidiaries**. The Company has been duly incorporated or organized and is validly existing and in good standing under the laws of Delaware or other jurisdiction of incorporation or organization, has full corporate or other power and authority necessary to own or lease its properties and conduct its business as presently conducted, and is duly qualified as a foreign corporation and in good standing in all jurisdictions in which the character of the property owned or leased or the nature of the business transacted by it makes qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect. The Company owns, directly or through subsidiaries, all of the issued outstanding equity securities of each of its subsidiaries. Each of the Company's subsidiaries has been duly incorporated or organized and is validly existing and in good standing under the laws of its jurisdiction of incorporation or organization, has full corporate or other power and authority necessary to own or lease its properties and conduct its business as presently conducted, and is duly qualified as a foreign corporation and in good standing in all jurisdictions in which the character of the property owned or leased or the nature of the business transacted by it makes qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

4.2 **Corporate Power; Authorization**. The Company has all requisite corporate power and authority, and the Company and its Board of Directors have taken all requisite corporate action, to authorize, execute and deliver this Agreement and the Warrants, to consummate the transactions contemplated herein and therein, including to sell, issue and deliver the Securities to the Purchasers, and to carry out and perform all of the Company's obligations hereunder and thereunder. This Agreement has been duly authorized, executed and delivered by the Company and, assuming the due authorization, execution and delivery by the Purchasers, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting the enforcement of creditors' rights generally and (ii) as limited by equitable principles generally, including any specific performance.

4.3 **Issuance and Delivery of the Securities**. The Shares have been duly authorized and, when issued and paid for in compliance with the provisions of this Agreement, will be validly issued, fully paid and nonassessable. The Warrants have been duly authorized by the Company and when executed and delivered by the Company will be valid and binding agreements of the Company, enforceable against the Company in accordance with their terms, except as the enforcement thereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles. The issuance and delivery of the Shares or Warrants is not subject to preemptive, co-sale, right of first refusal or any other similar rights of the stockholders of the Company or any other Person or any liens, encumbrances or restrictions, other than encumbrances under applicable securities laws. The Warrant Shares have been duly authorized and reserved for issuance and, when issued and delivered upon valid exercise of the Warrants in accordance therewith, will be validly issued, fully paid and nonassessable, and not subject to preemptive, co-sale, right of first refusal or any other similar rights of the stockholders of the Company or any other Person or any liens, encumbrances or restrictions, other than encumbrances under applicable securities laws or the Warrants. Assuming the accuracy of the representations made by the Purchasers in Section 5, the offer and issuance by the Company of the Securities is exempt from registration under the Securities Act.

4.4 **SEC Documents; Financial Statements; Independent Accountants**. The Company is subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and has filed or furnished or will file or furnish in a timely manner all reports, schedules, forms, statements and other documents that the Company was or is required to file with the Commission under either the Securities Act or the Exchange Act, for the one year preceding the date hereof (the foregoing documents (together with any documents filed by the Company under the Securities Act or Exchange Act, whether or not required), and in each case including all exhibits and schedules thereto and documents incorporated by reference therein and including all registration statements and prospectuses filed with the Commission, but excluding any information for which the Company has received confidential treatment from the Commission, being collectively referred to herein as the "***SEC Documents***"). As of their respective filing or furnishing dates (or, if amended prior to the date of this Agreement, when amended), all SEC Documents (including any audited or unaudited financial statements and any notes thereto or schedules included therein) complied in all material respects with the requirements of the Securities Act or the Exchange Act, as the case may be, and the rules and regulations of the Commission promulgated thereunder. None of the SEC Documents as of their respective filing or furnishing dates contained any untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they were made, not misleading. There are no material outstanding or unresolved comments in comment letters from the staff of the Division of Corporation Finance of the Commission with respect to any SEC Documents. The financial statements (including the notes thereto) of the Company (other than any pro forma financial statements included in any SEC Document) set forth in the SEC Documents (the "***Financial Statements***") comply in all material respects with applicable accounting requirements and with the published rules and regulations of the Commission with respect thereto. The Financial Statements have been prepared in accordance with GAAP consistently applied (except as may otherwise be specified in such Financial Statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP) during the periods involved and fairly present, in all material respects, the financial position of the Company at the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal recurring adjustments). Except as set forth in the Financial Statements filed prior to the date hereof, the Company has not incurred any liabilities, contingent or otherwise, except those incurred in the ordinary course of business, consistent (as to amount and nature) with past practices since the date of such Financial Statements, none of which, individually or in the aggregate, have had or would reasonably be expected to have a Material Adverse Effect. The accountants who certified the Financial Statements are independent public accountants as required by the Securities Act and the Exchange Act and the regulations thereunder and the Public Company Accounting Oversight Board.

4.5 **Capitalization**. The authorized capital stock of the Company consists of 1,000,000,000 shares of Common Stock and 30,000,000 shares of preferred stock. As set forth in the SEC Documents as of the date set forth therein, all of the Company's outstanding shares of capital stock have been duly authorized and validly issued and are fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and were not issued in violation of or subject to any preemptive right or other rights to subscribe for or purchase securities. Except as disclosed in the SEC Documents and stock options issued by the Company in the ordinary course of business since September 30, 2023, there are no existing options, warrants, calls, subscriptions or other rights, agreements, arrangements or commitments of any character, relating to the issued or unissued capital stock of the Company, obligating the Company to issue, transfer, sell, redeem, purchase, repurchase or otherwise acquire or cause to be issued, transferred, sold, redeemed, purchased, repurchased or otherwise acquired any capital stock or voting debt of, or other equity interest in, the Company or securities or rights convertible into or exchangeable for such shares or equity interests or obligations of the Company to grant, extend or enter into any such option, warrant, call, subscription or other right, agreement, arrangement or commitment. Neither the execution of this Agreement nor the issuance of Common Stock or other securities pursuant to any provision of this Agreement or the Warrants will give rise to any preemptive rights or rights of first refusal on behalf of any Person or result in the triggering of any anti-dilution or other similar rights (including a rights distribution under any "poison pill" plan or similar arrangement). Other than the Common Stock, there are no other shares of any other class or series of capital stock of the Company issued or outstanding. The Company's Certificate of Incorporation, as amended and as in effect on the date hereof (the "***Certificate of Incorporation***"), and the Company's Bylaws, as amended and as in effect on the date hereof (the "***Bylaws***"), are included in the SEC Documents, and the Company shall not amend or otherwise modify the Certificate of Incorporation or Bylaws prior to the earlier of the Closing or the termination of this Agreement in accordance with its terms. There are no voting agreements, buy-sell agreements, option or right of first purchase agreements or other agreements of any kind among the Company and any of the security holders of the Company relating to the securities of the Company held by them.

4.6 **Litigation**. There are no legal, governmental or regulatory actions, suits, investigations, charges, claims, complaints, audits, inquiries or other proceedings pending or, to the Knowledge of the Company, threatened against the Company or any of its subsidiaries, before or by any court, regulatory body or administrative agency or any other governmental agency or body, domestic or foreign, which actions, suits or proceedings, individually or in the aggregate, would reasonably be expected to (a) challenge this Agreement or prohibit or delay the transactions contemplated herein or (b) have a Material Adverse Effect. Neither the Company nor any of its subsidiaries, is a party to or subject to the provisions of any injunction, judgment, decree or order of any court, regulatory body, administrative agency or other governmental agency or body that might have a Material Adverse Effect. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company under the Securities Act or the Exchange Act.

4.7 **Governmental Consents**. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, or local governmental authority or the Trading Market on the part of the Company is required in connection with the consummation of the transactions contemplated by this Agreement except for, if applicable, the filing of a Form D with the Commission under the Securities Act and compliance with the securities and blue sky laws in the states and other jurisdictions in which shares of Common Stock are offered and/or sold, which compliance will be effected by the Company in accordance with such laws.

4.8 **No Default or Consents**. Neither the Company nor any of its subsidiaries, is in violation or default under its organizational documents. Neither the execution, delivery or performance of this Agreement or the Warrants by the Company nor the consummation of any of the transactions contemplated hereby or thereby (including the issuance, sale and delivery by the Company of the Securities) will: (i) give rise to a right to terminate or accelerate the due date of any payment due under, or conflict with or result in the breach of any term or provision of, or constitute a default (or an event which with notice or lapse of time or both would constitute a default) under, or require any consent or waiver under, or result in the execution or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to the terms of, any indenture, mortgage, deed of trust or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which either or them or any of their respective properties or businesses are bound, or any franchise, license, permit, judgment, decree, order, statute, rule or regulation (including federal and state securities laws and regulations), and the rules and regulations, assuming the correctness of the representations and warranties made by the Purchasers herein, of any self-regulatory organization to which the Company or any of its subsidiaries or their securities are subject applicable to the Company, or (ii) violate or conflict with any provision of the Certificate of Incorporation or the Bylaws, except in the case of clause (i) as would not cause, either individually or in the aggregate, a Material Adverse Effect, and except for such consents or waivers which have already been obtained and are in full force and effect.

4.9 **No Material Adverse Change**. Since September 30, 2023, except as specifically disclosed in the SEC Documents, there have been no events, occurrences or developments that have had or would reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect. Except for the transactions contemplated by this Agreement, no event, liability or development has occurred or exists with respect to the Company or any of its subsidiaries or their respective businesses, properties, operations or financial conditions that would be required to be disclosed by the Company under applicable securities laws at the Effective Date that has not been publicly disclosed at least one Trading Day prior to the Effective Date.

4.10 **No General Solicitation**. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D promulgated under the Securities Act) in connection with the offer or sale of the Securities.

4.11 **No Integrated Offering.** None of the Company or any of its Affiliates, or any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would require registration of any of the Securities under the Securities Act or cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of the Securities Act or any applicable stockholder approval provisions, including under the rules and regulations of the Trading Market.

4.12 **Sarbanes-Oxley Act**. The Company is in material compliance with the requirements of the Sarbanes-Oxley Act of 2002 that are effective and applicable to the Company as of the date hereof, and the rules and regulations promulgated by the Commission thereunder that are effective and applicable to the Company as of the date hereof.

4.13 **Intellectual Property.** To the Knowledge of the Company, the Company and its subsidiaries own, possess, license or have rights to use, on terms that the Company believes to be reasonable, all patents, patent applications, trademarks, trademark applications, service marks, trade names, copyrights, licenses, trade secrets, know-how and other similar rights that are necessary or material for use in connection with the businesses of the Company and its subsidiaries as described in the SEC Documents (collectively, the "***Intellectual Property Rights***"). Neither the Company nor any of its subsidiaries has received a written notice that the Intellectual Property Rights used by the Company or any subsidiary violates or infringes upon the rights of any Person. To the Knowledge of the Company, (i) all such Intellectual Property Rights are enforceable, (ii) there is no existing infringement by another Person of any of the Intellectual Property Rights and (iii) there is no pending or threatened action, suit, proceeding or claim by others challenging the Company's Intellectual Property Rights. The Company and its subsidiaries have taken reasonable security measures to protect the secrecy and confidentiality of the Intellectual Property Rights (excluding any patents or patent applications that have or will become public), except where the failure to do so would not, individually or in the aggregate, have a Material Adverse Effect. All material licenses or other material agreements under which the Company is granted rights to intellectual property, if any, are in full force and effect and, to the Knowledge of the Company, there is no material default by any other party thereto. The Company has no reason to believe that the licensors under such licenses and other agreements, if any, do not have and did not have all requisite power and authority to grant the rights to the intellectual property purported to be granted thereby.

4.14 **Disclosure.** The Company understands and confirms that the Purchasers will rely on the representations, warranties and covenants set forth in this Section 4 in effecting the transactions contemplated by this Agreement. All due diligence materials regarding the Company and its business and the transactions contemplated hereby (including the information referred to in Section 5.8 hereof), furnished by or on behalf of the Company to the Purchasers upon their request are, when taken together with the SEC Documents, true and correct in all material respects and do not contain any untrue statement of material fact or omit to state a material fact necessary in order to make the statements made therein, in light of the circumstances in which they were made, not misleading. The Company understands and agrees that each Purchaser, in making its decision to enter into this Agreement and purchase its Securities, will rely on such due diligence materials and SEC Documents. The Company confirms that neither it nor any officers or directors has provided any Purchaser or its agents or counsel with any information that constitutes or might constitute material, nonpublic information, other than with respect to the existence of, and the material terms and conditions of, the transactions contemplated by this Agreement. The Company understands and confirms that each of the Purchasers will rely on the foregoing representations in effecting transactions in securities of the Company.

4.15 **Contracts.**

(a) Each indenture, contract, lease, mortgage, deed of trust, note agreement, loan or other agreement or instrument of a character that is required to be described or summarized in the SEC Documents or to be filed as an exhibit to the SEC Documents under the Exchange Act and the rules and regulations promulgated thereunder (collectively, the "***Material Contracts***") is so described, summarized or filed.

(b) The Material Contracts to which the Company or any of its subsidiaries is a party have been duly and validly authorized, executed and delivered by the Company or such subsidiary and constitute the legal, valid and binding agreements of the Company or such subsidiary, enforceable by and against the Company and its subsidiaries in accordance with their respective terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or other similar laws relating to enforcement of creditors' rights generally, and general equitable principles relating to the availability of remedies, except as rights to indemnity or contribution may be limited by federal or state securities laws. Neither the Company nor any of its subsidiaries nor, to the Knowledge of the Company, any third party has violated any provision of, or failed to perform any obligation required under the provisions of, any of the Material Contracts. Neither the Company nor any of its subsidiaries nor, to the Knowledge of the Company, any third party is in breach or default, or has received written notice of breach or default, of any of the Material Contracts. To the Knowledge of the Company, no event has occurred that, with notice or lapse of time or both, would constitute such a breach or default pursuant to any Material Contract by the Company or any of its subsidiaries, or, to the Knowledge of the Company, any other party thereto, and, as of the date of this Agreement, neither the Company nor any of its subsidiaries has received written notice of the foregoing or from the counterparty to any Material Contract (or, to the Knowledge of the Company, any of such counterparty's Affiliates) regarding an intent to terminate, cancel, or modify any Material Contract (whether as a result of a change of control or otherwise).

4.16 **Properties and Assets.** The Company and its subsidiaries have good and marketable title to all the properties and assets described as owned by them in the latest Financial Statements set forth in the SEC Documents, free and clear of all liens, mortgages, pledges or encumbrances of any kind except (a) those, if any, reflected in such Financial Statements or (b) those that are not material in amount and do not adversely affect the use made and proposed to be made of such property by the Company or any subsidiary. The Company and its subsidiaries hold their respective leased properties under valid and binding leases, except as would not have a Material Adverse Effect. The Company and its subsidiaries own or lease all such properties as are materially necessary to their respective operations as now conducted.

4.17 **Compliance and Regulatory**. The Company and its subsidiaries are in compliance in all material respects with all applicable Laws of the jurisdictions in which they are conducting their business, including all applicable local, state and federal environmental Laws (including Laws relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances), and all applicable Laws enforced by the United States Food and Drug Administration (the "***FDA***"), (including the Federal Food, Drug And Cosmetic Act, as amended, and the regulations promulgated thereunder) or any applicable laws enforced by equivalent Governmental Entities outside the United States, except where failures to be so in compliance, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect. Any preclinical tests and studies or clinical trials conducted by, on behalf of, or sponsored by the Company or any of its subsidiaries ("***Studies***"), were and, if still ongoing, are being conducted in all material respects in accordance with all applicable laws and regulations governing the conduct of such Studies, the protocols, procedures and controls submitted to the FDA or any foreign Governmental Entity exercising comparable authority (together with the FDA, the "***Regulatory Authorities***"), and any conditions of approval and policies imposed by any institutional review board, ethics review board or other committee responsible for the oversight of such preclinical tests and studies or clinical trials. The descriptions of the Studies contained in the SEC Documents are accurate in all material respects; to the Knowledge of the Company, there are no other preclinical studies and clinical trials, the results of which are inconsistent with or would call into question the results described in the SEC Documents in any material respect; and neither the Company nor any of its subsidiaries has received any written notice or correspondence from any institutional review board, the FDA or any other Regulatory Authority exercising comparable authority requiring or threatening the termination, suspension, or clinical hold of Studies, where such termination, suspension or clinical hold would reasonably be expected to have a Material Adverse Effect, and to the Knowledge of the Company, there are no reasonable grounds for the same.

4.18 **Taxes**. The Company and its subsidiaries have filed on a timely basis (giving effect to extensions) all required federal, state and foreign income and franchise tax returns and have timely paid or accrued all taxes shown as due thereon, including interest and penalties, and, to the Knowledge of the Company, there is no tax deficiency that has been or might be asserted or threatened against it or them that could have a Material Adverse Effect. All tax liabilities accrued through the date hereof have been adequately provided for on the books of the Company. There are no liens for material taxes upon the assets of the Company or any of its subsidiaries other than for current taxes not yet due and payable or for taxes that are being contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP has been made in the Company's most recent financial statements included in the SEC Documents.

4.19 **Investment Company.** The Company is not, and immediately after receipt of payment for the Securities will not be, an "investment company" or an "affiliated person" of, or "promoter" or "principal underwriter" for an investment company, within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission promulgated thereunder.

4.20 **Insurance.** The Company maintains insurance underwritten by insurers of recognized financial responsibility, of the types and in the amounts that the Company reasonably believes is adequate for the businesses of the Company and its subsidiaries, including directors' and officers' liability insurance and insurance covering all real and personal property owned or leased by the Company or any of its subsidiaries against theft, damage, destruction, acts of vandalism and all other risks customarily insured against and against such risks which the Company believes it is prudent to insure against, with such deductibles as are customary for companies in the same or similar business, all of which insurance is in full force and effect.

4.21 **Price of Common Stock.** The Company has not taken, and will not take, and no Person acting on its behalf has taken or will take, directly or indirectly, any action designed to cause or result in, or that has constituted or that might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.22 **Governmental Permits, Etc.** The Company and its subsidiaries have all franchises, licenses, permits, certificates and other authorizations from such federal, state or local government or governmental agency, department or body that are currently necessary for the operation of their respective businesses as currently conducted, including, without limitation, all such certificates, approvals, authorizations, exemptions, licenses and permits required by the FDA or any other comparable Governmental Entities, including other Regulatory Authorities (collectively, "***Permits***"), except where the failure to possess such Permits would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any written notice requiring or threatening any revocation or modification of any such Permits, where such revocation or modification would reasonably be expected to have a Material Adverse Effect.

4.23 **Internal Control over Financial Reporting; Disclosure Controls.** The Company maintains internal control over financial reporting (as such term is defined in paragraph (f) of Rule 13a-15 under the Exchange Act) as required by Rule 13a-15 under the Exchange Act. Except as disclosed in the SEC Documents, since the end of the Company's most recent audited fiscal year, there has been no material weakness in the design or operation of the Company's internal control over financial reporting (whether or not remediated) which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information. The Company's "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Exchange Act) are designed to provide reasonable assurance that all information (both financial and non-financial) required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Commission, and that all such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure.

4.24 **Foreign Corrupt Practices.** Neither the Company nor any of its subsidiaries, nor any director or officer, nor, to the Knowledge of the Company, any agent, employee or other Person acting on behalf of the Company or any of its subsidiaries, has, in the course of its actions for, or on behalf of, the Company or any subsidiary (a) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (b) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (c) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 or any similar Law; or (d) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any foreign or domestic government official or employee.

4.25 **Employee Relations.** No material labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company or any of its subsidiaries, exists or, to the Knowledge of the Company, is threatened or imminent. No executive officer of the Company (as defined in Rule 501(f) promulgated under the Securities Act) has notified the Company that such officer intends to leave the Company or otherwise terminate such officer's employment with the Company. To the Knowledge of the Company, no executive officer of the Company is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement, non-competition agreement, or any other agreement or any restrictive covenant involving or otherwise affecting such executive officer's relationship with the Company, and the continued employment of each such executive officer does not subject the Company to any material liability with respect to any of the foregoing matters.

4.26 **ERISA.** The Company and its subsidiaries are in compliance in all material respects with all presently applicable provisions of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"); no "reportable event" (as defined in ERISA) has occurred with respect to any "pension plan" (as defined in ERISA) for which the Company or any subsidiary would have any material liability; neither the Company nor any of its subsidiaries has not incurred or expects to incur material liability under (a) Title IV of ERISA with respect to termination of, or withdrawal from, any "pension plan" or (b) Sections 412 or 4971 of the Internal Revenue Code of 1986, as amended, including the regulations and published interpretations thereunder (the "***Code***"); and each "Pension Plan" for which the Company or any of its subsidiaries would have liability that is intended to be qualified under Section 401(a) of the Code is so qualified in all material respects and to the Knowledge of the Company, nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

4.27 **Registration Rights and Other Stockholder Agreements.** No Person has any right to cause the Company to effect the registration under the Securities Act covering the transfer of any securities of the Company and there are no other stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the Knowledge of the Company, between or among any of the Company's stockholders.

4.28 **Trading Market Compliance.** The Company has not, in the previous twelve (12) months, received, nor is there any reasonable basis for, (i) written notice from the Trading Market that the Company is not in compliance with the listing or maintenance requirements of the Trading Market that would result in immediate delisting or (ii) any notification, Staff Delisting Determination, or Public Reprimand Letter (as such terms are defined in applicable listing rules of the Trading Market) that requires a public announcement by the Company of any noncompliance or deficiency with respect to such listing or maintenance requirements. The Company is in compliance with all listing and maintenance requirements of the Trading Market on the date hereof. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.

4.29 **No** "**Bad Actor**" **Disqualification.** No "bad actor" disqualifying event described in Rule 506(d)(1)(i)-(viii) of the Securities Act (a "***Disqualification Event***") is applicable to the Company or to any Company Covered Person (as defined below), except for a Disqualification Event to which Rule 506(d)(2)(ii-iv) or (d)(3) is applicable. "***Company Covered Person***" means, with respect to the Company as an "issuer" for purposes of Rule 506 promulgated under the Securities Act, any person listed in the first paragraph of Rule 506(d)(1).

4.30 **OFAC.** None of the Company, any of its subsidiaries, any director, officer, nor, to the Knowledge of the Company, any agent, employee, Affiliate or representative of the Company or any of its subsidiaries is a Person that is, or is more than 50 percent owned in the aggregate by or acting on behalf of one or more Persons that are, currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, His Majesty's Treasury, or other relevant sanctions authority (collectively, "***Sanctions***"), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions; and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partners or other Person, to fund any activities of or business (i) with any Person, or in any country or territory, that, at the time of such funding, is a designated target of Sanctions, (ii) in or involving a country or territory which at the time of such funding is the subject of comprehensive country-wide or territory-wide Sanctions, or (iii) in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. The Company has not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

4.31 **Compliance with Anti-Money Laundering Laws**. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance in all material respects with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental or regulatory agency (collectively, the "***Anti-Money Laundering Laws***") and no action, suit or proceeding by or before any court or governmental or regulatory agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the Knowledge of the Company, threatened.

4.32 **No Additional Agreements.** The Company has no other agreements or understandings (including side letters) with any Purchaser or any other Person to purchase Securities on terms more favorable to such Purchaser than as set forth herein.

4.33 **Transactions with Affiliates.** None of the officers or directors of the Company, or to the Knowledge of the Company, the Company's stockholders, the officers or directors of any stockholder of the Company, or any family member or affiliate of any of the foregoing, has either directly or indirectly any interest in, or is a party to, any transaction that would be required to be disclosed as a related party transaction pursuant to Item 404 of Regulation S-K promulgated under the Securities Act.

4.34 **Security.** Except as would not reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "***IT Systems***") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, and are free and clear of all material Trojan horses, time bombs, malware and other malicious code. Except as would not reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls designed to maintain and protect the confidentiality, integrity, availability, privacy and security of all sensitive, confidential or regulated data ("***Confidential Data***") used or maintained in connection with their businesses and Personal Data, and the integrity, availability continuous operation, redundancy and security of all IT Systems. "***Personal Data***" means the following data used in connection with the Company's and its subsidiaries' businesses and in their possession or control: (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or other tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) information that identifies, relates to, or may reasonably be used to identify an individual; (iii) any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional; (iv) an individual's health insurance policy number or subscriber identification number, any unique identifier used by a health insurer to identify the individual, or any information in an individual's application and claims history; (v) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "***HIPAA***"); (vi) any information which would qualify as "personal data," "personal information" (or similar term) under the Privacy Laws (as defined in Section 4.36); and (vii) any other piece of information that alone, or combined with other information, allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. Except as would not reasonably be expected to have a Material Adverse Effect, during the past three (3) years, there have been no breaches, outages or unauthorized uses of or accesses to the IT Systems, Confidential Data, and Personal Data.

4.35 **Compliance with Data Privacy Laws.** The Company and its subsidiaries are, and at all prior times during the last three (3) years were, in material compliance with all applicable state and federal data privacy and security Laws and regulations regarding the collection, use, storage, retention, disclosure, transfer, disposal, or any other processing (collectively "***Process***" or "***Processing***") of Personal Data, including, to the extent applicable, HIPAA, the California Consumer Privacy Act, and the European Union General Data Protection Regulation (EU 2016/679) (collectively, the "***Privacy Laws***"). To comply with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take all appropriate steps necessary to ensure compliance in all material respects with their policies and procedures relating to data privacy and security, and the Processing of Personal Data and Confidential Data (the "***Privacy Statements***"). The Company and its subsidiaries have, except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, at all times since January 1, 2022 provided accurate notice of its Privacy Statements then in effect to its clients, employees, third party vendors and representatives. None of such disclosures made or contained in any Privacy Statements have been materially inaccurate, misleading, incomplete, or in material violation of any Privacy Laws. The Company further represents that neither it nor any of its subsidiaries: (i) has received notice of any actual or potential claim, complaint, proceeding, regulatory proceeding or liability under or relating to, or actual or potential violation of, any of the Privacy Laws, contracts related to the Processing of Personal Data or Confidential Data, or Privacy Statements, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law or contract; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

SECTION 5. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PURCHASERS.

Each Purchaser, severally and not jointly, represents and warrants to and covenants with the Company and each of the Placement Agents that:

5.1 **Risk.** Such Purchaser, taking into account the personnel and resources it can practically bring to bear on the purchase of the Securities contemplated hereby, is knowledgeable, sophisticated and experienced in making, and is qualified to make, decisions with respect to investments in securities presenting an investment decision like that involved in the purchase of the Securities, including investments in securities issued by the Company, and has requested, received, reviewed and considered all information such Purchaser deems relevant (including the SEC Documents) in making an informed decision to purchase the Securities. Such Purchaser (a) has conducted its own investigation of the Company and the Securities and it has not relied on any statements or other information provided by the Placement Agents concerning the Company or the Securities or the offer and sale of the Securities, (b) has had access to, and an adequate opportunity to review, financial and other information as it deems necessary to make its decision to purchase the Securities, (c) has been offered the opportunity to ask questions of the Company and received answers thereto, including on the financial information, as it deemed necessary in connection with its decision to purchase the Securities, and (d) has made its own assessment and has satisfied itself concerning the relevant tax and other economic considerations relevant to its investment in the Securities. Such Purchaser is able to fend for itself in the transactions contemplated herein; has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its prospective investment in the Securities; and has the ability to bear the economic risks of its prospective investment in the Securities and can afford the complete loss of such investment.

5.2 **Purchase for Investment.** Purchaser is acquiring the Securities pursuant to this Agreement for its own account for investment only and with no present intention of distributing any of such Securities or any arrangement or understanding with any other Persons regarding the distribution of such Securities, except in compliance with Section 5.4.

5.3 **Reliance.** Such Purchaser understands that the Securities are being offered and sold to it in reliance upon specific exemptions from the registration requirements of the Securities Act, the rules and regulations thereunder, and state securities laws and that the Company is relying upon the truth and accuracy of, and such Purchaser's compliance with, the representations, warranties, agreements, acknowledgments and understandings of such Purchaser set forth herein in order to determine the availability of such exemptions and the eligibility of such Purchaser to acquire the Securities. If any of the representations and warranties made by such Purchaser herein are no longer accurate in all material respects prior to Closing, such Purchaser shall promptly notify the Company. If such Purchaser is acquiring the Securities as a fiduciary or agent for one or more investor accounts, it represents that it has sole investment discretion with respect to each such account and it has full power to make the foregoing representations, acknowledgements and agreements on behalf of such account.

5.4 **Compliance with the Securities Act**. Such Purchaser will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the securities purchased hereunder except in compliance with the Securities Act, applicable blue sky laws, and the rules and regulations promulgated thereunder.

5.5 **Accredited Investor.** Such Purchaser is (a) a qualified purchaser (as defined in Section 2(a)(51)(A) of the Investment Company Act of 1940, as amended), (b) a qualified institutional buyer (as defined in Rule 144A of the Securities Act), and/or (c) an accredited investor as described in Rule 501(a)(1), (2), (3) or (7) of the Securities Act. Purchaser acknowledges that it has been informed that the offering of the Securities meets the exemptions from filing under Financial Industry Regulatory Authority ("***FINRA***") Rule 5123(b)(1)(B), (C) or (J).

5.6 **Power and Authority.** Such Purchaser has all requisite corporate power, and has taken all requisite corporate action, to authorize, execute and deliver this Agreement and each of the other agreements and instruments contemplated herein to which the Purchaser is a party, to consummate the transactions contemplated herein and therein and to carry out and perform all of such Purchaser's obligations hereunder and thereunder. Upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of such Purchaser, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting the enforcement of creditors' rights generally and (ii) as limited by equitable principles generally, including any specific performance.

5.7 **Broker Dealer.** Such Purchaser is not a broker or dealer registered pursuant to Section 15 of the Exchange Act.

5.8 **Sophisticated Investor**. Such Purchaser (a) acknowledges that it is a sophisticated investor engaged in the business of assessing and assuming investment risks with respect to securities, including securities such as the Units, Shares, Warrants and Warrant Shares, and further acknowledges that the Company is entering into this Agreement in reliance on this acknowledgment and said Purchaser's understanding, acknowledgment and agreement that the Purchaser may have agreed in writing with the Company or the Placement Agents to receive information regarding certain confidential matters as part of its due diligence review that may represent material, non-public information of the Company, (b) acknowledges that it is aware of the restrictions imposed by United States securities laws on the purchase or sale of securities by any Person who has received material, non-public information from the issuer of such securities and on the communication of such information to any other Person when it is reasonably foreseeable that such other Person is likely to purchase or sell such securities in reliance upon such information, (c) is an institutional account as defined in FINRA Rule 4512(c), (d) is a sophisticated investor, experienced in investing in private equity transactions and capable of evaluating investment risks independently, both in general and with regard to all transactions and investment strategies involving a security or securities, and (e) has exercised independent judgment in evaluating our participation in the purchase of the Securities. Purchaser acknowledges that the offering of the Securities meets (i) the exemptions from filing under FINRA Rule 5123(b)(1)(A) and (ii) the institutional customer exemption under FINRA Rule 2111(b).

5.9 **Other Securities Transactions.** Such Purchaser has not, either directly or indirectly through an Affiliate, agent or representative of the Company, engaged in any Short Sales or any transaction in the securities of the Company other than with respect to the transactions contemplated herein, since the time that the Purchaser was first contacted by the Company or the Placement Agents or any other Person regarding the transactions contemplated hereby until the date hereof. Notwithstanding the foregoing, (a) in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement and (b) in the case of a Purchaser that is affiliated with other funds or investment vehicles or whose investment advisor or sub-advisor that routinely acts on behalf of or pursuant to an understanding with such Purchaser is also an investment advisor or sub-advisor to other funds or investment vehicles, the representation set forth above shall only apply with respect to the personnel of such other funds or investment vehicles or such investment advisor or sub-advisor who had knowledge of the transactions contemplated hereby and not with respect to any personnel who have been effectively walled off by appropriate information barriers.

5.10 **Independent Advice.** Such Purchaser understands that nothing in this Agreement or any other materials presented to such Purchaser by or on behalf of the Company in connection with the purchase and sale of the Securities constitutes legal, tax or investment advice. Such Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Securities. In connection with the issue and purchase of the Securities, the Placement Agents have acted solely as the agent of the Company in this placement of the Securities and neither Placement Agent nor any of their respective affiliates have acted as underwriters or as financial advisors or fiduciaries of such Purchaser, the Company or any other person or entity. The Placement Agents have not made and will not make any representation or warranty, whether express or implied, of any kind or character and have not provided any advice or recommendation in connection with the transactions contemplated hereby. No disclosure or offering document has been prepared in connection with the offer and sale of the Shares by any of the Placement Agents. Each Purchaser hereby acknowledges and agrees that none of the Placement Agents shall be liable to it (including in contract, tort, under federal or state securities laws or otherwise) for any action heretofore or hereafter taken or omitted to be taken by any of them in connection with the private placement of Securities hereunder, or for any improper payment made in accordance with the information provided by the Company. The Placement Agent will have no responsibility with respect to (a) any representations, warranties or agreements made by any person or entity under or in connection with the transactions contemplated hereby or any of the documents furnished pursuant thereto or in connection therewith, or the execution, legality, validity or enforceability (with respect to any person) of any thereof, or (b) the financial condition, business, or any other matter concerning the Company or the transactions contemplated hereby. The Placement Agents and their respective directors, officers, employees, representatives and controlling persons have made no independent investigation with respect to the Company or the Securities or the accuracy, completeness or adequacy as of any date of any information set forth in, or any omission from, any valuation or other materials that may have been provided or made available to the Purchaser in connection with the transactions contemplated hereby. Each Purchaser is not relying upon, and has not relied upon, any statement, representation or warranty made by any person, including, without limitation, the Placement Agents, any of its affiliates or any of its or their control persons, officers, directors and employees, in making its investment or decisions to invest in the Company, except for the statements, representations and warranties made by the Company and contained in this Agreement and the SEC Documents.

5.11 **Legends.** Such Purchaser understands that, until such time as the Securities may be sold pursuant to an effective registration statement or Rule 144 under the Securities Act ("***Rule 144***") (or any other applicable exemption from the registration requirements under the Securities Act), any certificates representing the Securities, whether maintained in a book entry system or otherwise, will bear one or more legends in substantially the following form and substance:

> "THE SECURITIES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE REOFFERED, SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, HYPOTHECATED OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION WHICH IS EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, IN EACH CASE IN ACCORDANCE WITH ALL APPLICABLE SECURITIES LAWS, AND, IN THE CASE OF A TRANSACTION EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, THE HOLDER WILL NOTIFY ANY SUBSEQUENT PURCHASER OF THE SECURITIES EVIDENCED BY THIS CERTIFICATE FROM IT OF SUCH RESALE RESTRICTIONS."

In addition, any stock certificates, whether maintained in a book entry system or otherwise, representing the Securities may contain any legend required by the blue sky laws of any state to the extent such laws are applicable to the sale of such Securities hereunder. The Company shall promptly help facilitate the removal of such legend as soon as it is legally permitted to do so under Rule 144, or to facilitate any transfer of the Securities under Rule 144 that may be requested by Purchasers, but shall not be obligated to incur any material, noncustomary costs or expenses in taking such actions other than as set forth herein.

5.12 **Restricted Securities.** Such Purchaser understands that the Securities are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such Securities may be resold without registration under the Securities Act only in certain limited circumstances. Accordingly, such Purchaser represents that it is familiar with Rule 144 of the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

5.13 **Beneficial Ownership**. The purchase by the Purchaser of the Securities issuable to it at the Closing will not result in the Purchaser (individually or together with any other Person with whom the Purchaser has identified, or will have identified, itself as part of a "group" in a public filing made with the Commission involving the Company's securities, where such aggregation would be made according to Section 13(d) of the Exchange Act) acquiring, or obtaining the right to acquire, in excess of 19.999% of the outstanding shares of Common Stock or the voting power of the Company on a post-transaction basis that assumes that such Closing shall have occurred. The Purchaser does not presently intend to, alone or together with others, make a public filing with the Commission to disclose that it has (or that it together with such other Persons have) acquired, or obtained the right to acquire, as a result of such Closing (when added to any other securities of the Company that it or they then own or have the right to acquire), in excess of 19.99% of the outstanding shares of Common Stock or the voting power of the Company on a post-transaction basis that assumes that each Closing shall have occurred (including assuming the effectiveness of any "blocker" or similar limitations on beneficial ownership contained in the applicable documentation for the Securities).

SECTION 6. REGISTRATION OF THE SECURITIES AND COMPLIANCE WITH THE SECURITIES ACT.

6.1 **Registration Procedures and Expenses**.

(a) **Secondary Registration Statement.** The Company shall prepare and file, on or before the date that is forty-five (45) days after the Closing (the "***Filing Deadline***"), with the Commission a Registration Statement on Form S-1 (or, if the Company determines, in its sole discretion, it is eligible to register for resale the Shares and Warrant Shares (together with any shares of capital stock issued or issuable, from time to time, upon any reclassification, share combination, share subdivision, stock split, share dividend or similar transaction or event or otherwise as a distribution on, in exchange for or with respect to any of the foregoing, in each case held at the relevant time by a Purchaser the "***Registrable Securities***") on Form S-3, such registration shall be on Form S-3), as appropriate (the "***Secondary Registration Statement***"), relating to and providing for the resale of the Shares and Warrant Shares by the Purchasers on a continuous basis pursuant to Rule 415 under the Securities Act or, if Rule 415 is not available for offers and sales of the Registrable Securities, by such other means of distribution of Registrable Securities as the Purchasers may reasonably specify. Notwithstanding the foregoing, if the Commission prevents the Company from including any or all of the Registrable Securities on the Secondary Registration Statement due to limitations on the use of Rule 415 of the Securities Act for the resale of the Registrable Securities (and notwithstanding that the Company used diligent efforts to advocate with the staff of the Commission for the registration of all or a greater portion of the Registrable Securities), the Secondary Registration Statement shall register for resale such number of Registrable Securities that is equal to the maximum number of Registrable Securities as is permitted by the Commission. In such event, the number of Registrable Securities for which resale is to be registered for each selling shareholder named in the Secondary Registration Statement shall be reduced pro rata among all such selling shareholders and as promptly as practicable after being permitted to register additional Registrable Securities under Rule 415 under the Securities Act, the Company amend the Secondary Registration Statement or file one or more new registration statement(s) (such amendment or new registration statement, a "***Remainder Registration Statement***") to register such additional Registrable Securities not included in the Secondary Registration Statement and cause such Remainder Registration Statement to become effective as promptly as practicable after the filing thereof, but in any event no later than seventy-five (75) calendar days after the filing of such Remainder Registration Statement (the "***Remainder Effectiveness Deadline***"); *provided*, that the Remainder Effectiveness Deadline shall be extended to one-hundred and five (105) calendar days after the filing of such Remainder Registration Statement if the SEC notifies the Company that it will "review" such Remainder Registration Statement; *provided*, further, notwithstanding the foregoing, that the Company shall use reasonable best efforts to have such Remainder Registration Statement declared effective within five (5) business days after the date the Company is notified orally or in writing (whichever is earlier) by the Commission that such Remainder Registration Statement will not be reviewed or will not be subject to further review. Any failure by the Company to file the Secondary Registration Statement by the Filing Deadline or to effect the Secondary Registration Statement by the Effectiveness Deadline (as defined below) or the Remainder Registration Statement by the Remainder Effectiveness Deadline shall not otherwise relieve the Company of its obligations to file or effect the Secondary Registration Statement or Remainder Registration Statement set forth in this Section 6.1(a). In the event the Company files a Secondary Registration Statement on Form S-1, the Company shall use its commercially reasonable efforts to convert the Secondary Registration Statement (and any Remainder Registration Statement) to a Registration Statement on Form S-3 as soon as practicable after the Company is eligible to use Form S-3.

(b) The Company shall use its reasonable best efforts, subject to receipt of necessary information from the Purchasers, to cause the Commission to declare a Secondary Registration Statement covering the Shares and Warrant Shares effective as soon as practicable after the date of the filing thereof and in any event no later than the earlier of (i) thirty (30) days after such filing if the Secondary Registration Statement has been filed on Form S-3, and no later than seventy-five (75) days after such filing if such Secondary Registration Statement has been filed on Form S-1 (or, in either case, in the event the staff of the Commission reviews and has written comments, one-hundred and five days (105) after such filing), and in either case, no later than forty-five (45) days after such filing in the event the Secondary Registration Statement is not reviewed by the Commission and (ii) the third (3rd) Business Day after the date the Company is notified (orally or in writing, whichever is earlier) by the Commission that the Secondary Registration Statement will not be reviewed or will not be subject to further review (in either case, such date, the "***Effectiveness Deadline***").

(c) The Company shall promptly prepare and file with the Commission such amendments and supplements to the Secondary Registration Statement and the prospectus used in connection therewith as may be necessary to keep the Secondary Registration Statement effective until the earliest of (i) such time as all of the Shares and Warrant Shares purchased by the Purchasers pursuant to the terms of this Agreement have been sold or otherwise transferred by the holder thereof pursuant to and in a manner contemplated by such Secondary Registration Statement, (ii) such time as such Shares or Warrant Shares are sold pursuant to Rule 144 under circumstances in which any legend borne by such security relating to restrictions on transferability thereof, under the Securities Act or otherwise, is removed by the Company, or (iii) such time as the Shares and Warrant Shares become eligible for resale by non-Affiliates without any volume limitations or other restrictions pursuant to Rule 144(b)(1)(i) or any other rule of similar effect.

(d) Notwithstanding the foregoing obligations, the Company may, upon written notice to the Purchasers, for a reasonable period of time, not to exceed forty-five (45) days in the case of clauses (A) and (B) below, or thirty (30) days in the case of clause (C) below (each, a "***Blackout Period***"), delay the filing of a Secondary Registration Statement or a request for acceleration of the effective date, or suspend the effectiveness of any Secondary Registration Statement, in the event that (A) the Company is engaged in any activity or transaction or preparations or negotiations for any activity or transaction that the Company desires to keep confidential for business reasons, if the Company's Board of Directors, on the advice of the Company's outside legal counsel, determines in good faith that the public disclosure requirements imposed on the Company under the Securities Act in connection with the Secondary Registration Statement would require at that time disclosure of such activity, transaction, preparations or negotiations in the Secondary Registration Statement and such disclosure in the Secondary Registration Statement could result in material harm to the Company or its business transactions or activities and the non-disclosure of which in the Secondary Registration Statement would be expected, in the reasonable determination of the Company's Board of Directors, upon advice of the Company's outside legal counsel, to cause the Secondary Registration Statement to fail to comply with applicable disclosure requirements, (B) the Company does not yet have appropriate financial statements of any acquired or to be acquired entities necessary for filing, either because such financial statements are not yet available or despite the Company using reasonable best efforts to procure such financial statements or (C) any other event occurs that makes any statement of a material fact made in such Secondary Registration Statement, including any document incorporated by reference therein, untrue or that requires the making of any additions or changes in the Registration Statement in order to make the statements therein not misleading; provided, however, that in the case of a Blackout Period pursuant to clause (A) above, the Blackout Period shall terminate upon the earlier of (i) such forty-five (45) day period or (ii) the completion, resolution or public announcement of the relevant transaction or event. If the Company suspends the effectiveness of a Secondary Registration Statement pursuant to this Section 6.1(d), the Company shall, as promptly as reasonably practicable following the termination of the circumstance which entitled the Company to do so, take such actions as may be necessary to reinstate the effectiveness of such Secondary Registration Statement and give written notice to the Purchasers authorizing the Purchasers to resume offerings and sales pursuant to such Registration Statement. If as a result thereof the prospectus included in such Secondary Registration Statement has been amended or supplemented to comply with the requirements of the Securities Act, the Company shall enclose such revised prospectus with the notice to each Purchaser given pursuant to this Section 6. The Company shall be entitled to exercise its rights under this Section 6.1(d) not more than once in any six (6) month period; provided, however, that the aggregate number of days of all Blackout Periods hereunder shall not exceed sixty (60) days in any twelve (12) month period. After the expiration of any Blackout Period and without further request from any Purchaser, the Company shall effect the filing (or if required amendment or supplement) of the Secondary Registration Statement, or the filing of other documents, as necessary to allow the Purchasers to resell the Registrable Securities as set forth herein. In providing to a Purchaser the written notice of a Blackout Period as contemplated by the first sentence of this Section 6.1(d), the Company shall not (without the prior written consent of such Purchaser) disclose to such Purchaser any material nonpublic information giving rise to or otherwise associated with such Blackout Period.

(e) Upon notification by the Commission that the Secondary Registration Statement will not be reviewed or is not subject to further review by the Commission, the Company shall within three Business Days following the date of such notification request acceleration of such Secondary Registration Statement (with the requested effectiveness date to be not more than two Business Days later).

(f) The Company shall furnish to the Purchasers with respect to the Shares and Warrant Shares registered under any Secondary Registration Statement (and to each underwriter, if any, of such Shares and Warrant Shares) such number of copies of prospectuses and such other documents as the Purchaser may reasonably request, in order to facilitate the public sale or other disposition of all or any of the Shares and/or Warrant Shares by the Purchaser.

(g) The Company shall bear all expenses in connection with the procedures in paragraphs (a) through (f) of this Section 6.1 and the registration of the Shares and Warrant Shares pursuant to the Secondary Registration Statement, other than fees and expenses, if any, of counsel or other advisers to the Purchasers or underwriting discounts, brokerage fees and commissions incurred by the Purchaser, if any in connection with the offering of the Shares and Warrant Shares pursuant to the Secondary Registration Statement.

(h) In order to enable the Purchasers to sell the Shares and Warrant Shares under Rule 144 (or its successor) and any other rule or regulation of the Commission that may at any time permit the Purchasers to sell shares of Common Stock to the public without registration, the Company shall use its reasonable best efforts to comply with the requirements of Rule 144, including without limitation, the requirements of Rule 144(c)(1) with respect to public information about the Company and to timely file all reports and other documents required to be filed by the Company under the Exchange Act.

(i) The Company shall provide the Purchasers a reasonable opportunity to review and comment on all disclosures regarding the Purchasers and any plan of distribution proposed by them in connection with the preparation of any Secondary Registration Statement not less than five (5) Business Days prior to the filing of such Secondary Registration Statement. Notwithstanding anything to the contrary contained herein, in no event shall the Company be permitted to name any Purchaser or Affiliate of a Purchaser as an "underwriter" without the prior written consent of such Purchaser; *provided*, that if the Commission requires that a Purchaser be identified as a statutory underwriter in either the Secondary Registration Statement or a Remainder Registration Statement, such Purchaser will have the option, in its sole and absolute discretion, to either (i) have the opportunity to withdraw from the Secondary Registration Statement or Remainder Registration Statement, as the case may be, upon its prompt written request to the Company or (ii) be included as such in the Secondary Registration Statement or Remainder Registration Statement, as the case may be.

6.2 **Restrictions on Transfer**. Each Purchaser agrees that it will not effect any disposition of the Securities that would constitute a sale within the meaning of the Securities Act or pursuant to any applicable state securities laws, unless and until (1) there is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such registration statement or (2) such disposition is otherwise permitted by law, including pursuant to the procedures set forth in Rule 144 or any other applicable exemption from the registration requirements under the Securities Act. Notwithstanding the preceding sentence, no restriction shall apply to a transfer by a Purchaser that is (i) a partnership transferring to its partners or former partners in accordance with partnership interests, or (ii) a limited liability company transferring to its members or former members in accordance with member interests.

6.3 **Indemnification**. For the purpose of this Section 6.3: (i) the term "***Purchaser/Affiliate***" shall mean any officer, director, agent, partner, member, manager, stockholder, affiliate or employee of the Purchaser, and any investment adviser of a Purchaser, or any transferee who is an affiliate of a Purchaser, and any person who controls a Purchaser or any affiliate of the Purchaser within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (and the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of such controlling person); and (ii) the term "***Registration Statement***" shall include any preliminary prospectus, final prospectus (the "***Prospectus***"), free writing prospectus, exhibit, supplement or amendment included in or relating to, and any document incorporated by reference in, the Secondary Registration Statement and any Remainder Registration Statement pursuant to this Agreement.

(a) The Company agrees to indemnify and hold harmless each Purchaser and each Purchaser/Affiliate, against any losses, claims, damages, liabilities or expenses, joint or several, that such Purchaser or Purchaser/Affiliate incurs, under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Company, such consent not to be unreasonably withheld or delayed), insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) (i) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in the Registration Statement, including the Prospectus, financial statements and schedules, and all other documents filed as a part thereof or incorporated by reference therein, as amended at the time of effectiveness of the Registration Statement, including any information deemed to be a part thereof as of the time of effectiveness pursuant to paragraph (b) of Rule 430A under the Securities Act, or pursuant to Rules 430B, 430C or 434 under the Securities Act, or the Prospectus, in the form first filed with the Commission pursuant to Rule 424(b) under the Securities Act, or filed as part of the Registration Statement at the time of effectiveness if no Rule 424(b) filing is required or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state in any of them a material fact required to be stated therein or necessary to make the statements in the Registration Statement or any amendment or supplement thereto not misleading or in the Prospectus or any amendment or supplement thereto not misleading in light of the circumstances under which they were made, (ii) any violation or alleged violation by the Company or its agents of the Securities Act, the Exchange Act, or any other federal or state securities law or any rule or regulation thereunder, in connection with the performance or non-performance of its obligations under this Agreement or any action or inaction required of the Company in connection with any registration or (iii) arise out of or are based in whole or in part on any inaccuracy in the representations or warranties of the Company contained in this Agreement, breach of any covenant of the Company contained in this Agreement or any failure of the Company to perform its other obligations hereunder or under law, and will promptly reimburse each Purchaser and each Purchaser/Affiliate for any legal and other out-of-pocket expenses as such expenses are reasonably incurred and documented by such Purchaser or such Purchaser/Affiliate in connection with investigating, defending or preparing to defend, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the Company will not be liable for amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the written consent of the Company, which consent shall not be unreasonably withheld or delayed, and the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon (i) an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Prospectus or any amendment or supplement thereto in reliance upon and in conformity with written information furnished to the Company by or on behalf of the Purchaser expressly for use therein, (ii) the inaccuracy of any representation or warranty made by such Purchaser herein or (iii) any statement or omission in any Prospectus that is corrected in any subsequent Prospectus that was delivered to the Purchaser prior to the pertinent sale or sales by the Purchaser.

(b) Each Purchaser will severally, but not jointly, indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (and the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of such controlling person), against any losses, claims, damages, liabilities or expenses that the Company, each of its directors, each of its officers who signed the Registration Statement or controlling person (and the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of such controlling person) reasonably incurs, under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, but only if such settlement is effected with the written consent of such Purchaser, such consent not to be unreasonably withheld or delayed) insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based upon any untrue or alleged untrue statement of any material fact contained in the Registration Statement, the Prospectus, or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements in the Registration Statement or any amendment or supplement thereto not misleading or in the Prospectus or any amendment or supplement thereto not misleading in the light of the circumstances under which they were made, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Prospectus, or any amendment or supplement thereto, in reliance upon and in conformity with written information furnished to the Company by or on behalf of such Purchaser expressly for use therein; and will reimburse the Company, each of its directors, each of its officers who signed the Registration Statement or controlling person (and the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of such controlling person) for any legal and other expense reasonably incurred by the Company, each of its directors, each of its officers who signed the Registration Statement or controlling person (and the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of such controlling person) in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that (i) each Purchaser's aggregate liability under this Section 6 shall not exceed the amount of net proceeds received by such Purchaser on the sale of the Registrable Securities pursuant to the Registration Statement giving rise to such indemnification obligation, (ii) a Purchaser will not be liable for amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the written consent of such Purchaser, and (iii) a Purchaser will not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon the gross negligence, fraud or willful misconduct of the Company, any of Company's directors, any of Company's officers who signed the Registration Statement or any person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (or the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of such controlling person).

(c) Promptly after receipt by an indemnified party under this Section 6.3 of notice of the threat or commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 6.3 promptly notify the indemnifying party in writing thereof, but the omission to notify the indemnifying party will not relieve it from any liability that it may have to any indemnified party for contribution or otherwise under the indemnity agreement contained in this Section 6.3 to the extent it is not prejudiced as a result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it may wish, jointly with all other indemnifying parties similarly notified, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party, and the indemnifying party and the indemnified party shall have reasonably concluded, based on an opinion of counsel reasonably satisfactory to the indemnifying party, that there may be a conflict of interest between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties that are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of its election to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6.3 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed such counsel in connection with the assumption of legal defenses in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the expenses of more than one separate counsel, reasonably satisfactory to such indemnifying party, representing all of the indemnified parties who are parties to such action) or (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of action, in each of which cases the reasonable fees and expenses of counsel shall be at the expense of the indemnifying party. In no event shall any indemnifying party be liable in respect of any amounts paid in settlement of any action unless the indemnifying party shall have approved in writing the terms of such settlement; provided that such approval shall not be unreasonably withheld or delayed. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of or consent to the entry of any judgment in any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnification could have been sought hereunder by such indemnified party, unless such settlement or judgment (x) includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding, (y) imposes no liability or obligation on the indemnified person and (z) does not include any admission of fault, culpability, wrongdoing or malfeasance by or on behalf of the indemnified person. The indemnifying party shall notify the indemnified party promptly of the institution, threat or assertion of any proceeding in connection with, arising out of, as a result of, relating to or based upon the transactions contemplated by this Agreement of which the indemnifying party is aware. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such indemnified party and shall survive the transfer of any of the Securities by any of the Purchasers as permitted by this Agreement. Subject to the terms of this Agreement, all reasonable and documented fees and expenses of the indemnified party (including reasonable and documented fees and expenses to the extent incurred in connection with investigating or preparing to defend such proceeding in a manner not inconsistent with this Section 6.3) shall be paid to such indemnified party, as incurred, within ten (10) Business Days of written notice thereof to the indemnifying party, provided that the indemnified party shall promptly reimburse the indemnifying party for that portion of such fees and expenses applicable to such actions for which such indemnified party is finally judicially determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) not to be entitled to indemnification hereunder.

(d) If the indemnification provided for in this Section 6.3 is required by its terms but is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party under paragraphs (a), (b) or (c) of this Section 6.3 in respect to any losses, claims, damages, liabilities or expenses referred to herein, then each applicable indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of any losses, claims, damages, liabilities or expenses referred to herein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company and the Purchaser from the private placement of Securities hereunder or (ii) if the allocation provided by clause (i) above is not permitted by applicable Law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but the relative fault of the Company and the Purchaser in connection with the statements or omissions or inaccuracies in the representations and warranties in this Agreement and/or the Registration Statement that resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and each Purchaser on the other shall be deemed to be in the same proportion as the amount paid by such Purchaser to the Company pursuant to this Agreement for the Securities purchased by such Purchaser that were sold pursuant to the Registration Statement bears to the difference (the "***Difference***") between the amount such Purchaser paid for the Securities that were sold pursuant to the Registration Statement and the amount received by such Purchaser from such sale. The relative fault of the Company on the one hand and each Purchaser on the other shall be determined by reference to, among other things, whether the untrue or alleged statement of a material fact or the omission or alleged omission to state a material fact or the inaccurate or the alleged inaccurate representation and/or warranty relates to information supplied by the Company or by such Purchaser and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in paragraph (c) of this Section 6.3, any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in paragraph (c) of this Section 6.3 with respect to the notice of the threat or commencement of any threat or action shall apply if a claim for contribution is to be made under this paragraph (d); provided, however, that no additional notice shall be required with respect to any threat or action for which notice has been given under paragraph (c) for purposes of indemnification. The Company and the Purchaser agree that it would not be just and equitable if contribution pursuant to this Section 6.3(d) were determined solely by pro rata allocation (even if the Purchaser were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this paragraph. Notwithstanding the provisions of this Section 6.3(d), (i) no Purchaser shall be required to contribute any amount in excess of the amount by which the Difference exceeds the amount of any damages that such Purchaser has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission and (ii) each Purchaser's aggregate liability under this Section 6.3(d) shall not exceed the amount of net proceeds received by such Purchaser on the sale of the Registrable Securities pursuant to the Registration Statement giving rise to such indemnification or contribution obligation. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Purchasers' obligations to contribute pursuant to this Section 6.3(d) are several and not joint.

6.4 **Information Available**. The Company, upon the reasonable request of a Purchaser, shall make available for inspection by any deemed underwriter participating in any disposition pursuant to the Secondary Registration Statement and any attorney, accountant or other agent retained by deemed underwriter, all financial and other records, pertinent corporate documents and properties of the Company.

6.5 **Delay in Filing or Effectiveness of Secondary Registration Statement**. If a Secondary Registration Statement covering the Shares and Warrant Shares is not filed on or prior to the Filing Deadline, then for each day following the Filing Deadline or Effectiveness Deadline, as applicable, until but excluding the date the Company files, the Company shall, for each such day, pay each Purchaser with respect to any such failure, as liquidated damages and not as a penalty, an amount per thirty (30)-day period equal to 1.0% of the purchase price paid by such Purchaser for its Shares and Warrant Shares pursuant to this Agreement (calculated on a daily pro rata basis for any portion of such thirty (30)-day period prior to the cure of such failure); and for any such thirty (30)-day period (or earlier period if such failure is cured prior to thirty (30) days), such payment shall be made no later than three (3) Business Days following such thirty (30)-day period (or earlier period if such failure is cured prior to thirty (30) days). Notwithstanding any other provision herein, with respect to a Purchaser (i) the Filing Deadline and Effectiveness Deadline for a Secondary Registration Statement shall be extended, without default by or liquidated damages payable by the Company to such Purchaser pursuant to this Section 6.5 if the Company's failure to make such filing or obtain such effectiveness results from the failure of such Purchaser to timely provide the Company with information requested by the Company and necessary to complete a Secondary Registration Statement in accordance with the requirements of the Securities Act (in which case any such deadline would be extended with respect to all Registrable Securities held by such Purchaser until such time as the Purchaser provides such requested information), it being understood that the failure of such Purchaser to timely provide such information to the Company shall not affect the rights of other Purchasers herein, and (ii) in no event shall the Company be obligated to pay any liquidated damages pursuant to this Section 6.5 to more than one Purchaser in respect of the same Shares or Warrant Shares for the same period of time or in an aggregate amount that exceeds 5.0% of the purchase price paid by the Purchasers for the Shares and Warrant Shares pursuant to this Agreement. Such payments shall be made to the Purchasers in cash.

6.6 **No Piggyback on Registrations**. Neither the Company nor any of its security holders (other than the Purchasers in such capacity pursuant hereto) may include securities of the Company in the Secondary Registration Statement other than the Registrable Securities. The Company shall not file any other registration statements, other than any registration statements on Form S-4 or Form S-8 (each as promulgated under the Securities Act), prior to the Effective Date of the Secondary Registration Statement, provided that this Section 6.6 shall not prohibit the Company from filing amendments to registration statements filed prior to the date of this Agreement.

SECTION 7. NO BROKER'S FEE.

Each of the Company and the Purchasers (on a several but not joint basis) hereby represents that no broker, investment banker, financial advisor or other individual, corporation, general or limited partnership, limited liability company, firm, joint venture, association, enterprise, joint securities company, trust, unincorporated organization or other entity is entitled to any broker's, finder's, financial advisor's or other similar fee or commission in connection with the transactions contemplated by this Agreement, other than fees payable by the Company to the Placement Agents, which will be paid by the Company. The Company agrees to indemnify each Purchaser for any claims, losses or expenses incurred by such Purchaser as a result of the Company's representation in this Section 7 being untrue.

SECTION 8. COVENANTS.

8.1 **Blue Sky Filings**. The Company will take such action as the Company shall reasonably determine is necessary in order to obtain an exemption from, or to qualify the Securities for, sale to the Purchasers at the Closing pursuant to this Agreement under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon the written request of any Purchaser. Notwithstanding the foregoing, the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

8.2 **Transfer Taxes.** On the Closing Date, all stock transfer or other taxes (other than income taxes) that are required to be paid in connection with the issuance, sale and delivery of the Securities to the Purchasers hereunder will be fully paid or provided for by the Company and all laws imposing such taxes will have been fully complied with and the Purchasers and their respective Affiliates shall have no obligation therefor.

8.3 **Listing of Common Stock**. The Company shall promptly secure the listing of the Shares and Warrant Shares upon the Trading Market and each other national securities exchange and automated quotation system that requires an application by the Company for listing, if any, upon which shares of Common Stock are then listed (subject to official notice of issuance) and shall maintain such listing, so long as any other shares of Common Stock shall be so listed. The Company shall use its reasonable best efforts to maintain the Common Stock's listing on the Trading Market. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 8.3.

8.4 **Reservation of Common Stock.** As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue the Warrant Shares that are issuable upon the exercise of the Warrants.

8.5 **Equal Treatment of Purchasers.** No consideration (including any modification of documents related hereto) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of this Agreement or any documents related hereto unless the same consideration is also offered to all Purchasers hereunder. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class (subject to the proviso in the preceding sentence) and shall not in any way be construed as the Purchasers acting in concert or as a group (including a "group" within the meaning of Section 13(d)(3) of the Exchange Act) with respect to the purchase, disposition or voting of securities or otherwise. The Company does not have, and will not enter into, any agreement or understanding with any Purchaser that affords such Purchaser any rights or terms with respect to the transactions contemplated by this Agreement (including the exhibits hereto) that are more beneficial to such Purchaser than those afforded to all other Purchasers hereunder.

8.6 **Pledge of Securities**. The Company acknowledges and agrees that a Purchaser's Securities may be pledged by a Purchaser in connection with a bona fide margin agreement or other loan or financing arrangement that is secured by the Securities. The pledge of Securities shall not be deemed to be a transfer, sale or assignment of the Shares hereunder, and no Purchaser effecting a pledge of Securities shall be required to provide the Company with any notice thereof or otherwise make any delivery to the Company pursuant to this Agreement; provided that a Purchaser and its pledgee shall be required to comply with the provisions of this Agreement in order to effect a sale, transfer or assignment of Shares to such pledgee.

8.7 **Adjustments in Share Numbers and Prices**. In the event of any stock split, subdivision, dividend or distribution payable in shares of Common Stock (or other securities or rights convertible into, or entitling the holder thereof to receive directly or indirectly shares of Common Stock), combination or other similar recapitalization or event occurring after the date hereof and prior to the Closing, each reference this Agreement to a number of shares or a price per share shall be deemed to be amended to appropriately account for such event.

8.8 **Subsequent Equity Sales**.

(a) From the date hereof until the later of (i) the date the Secondary Registration Statement is declared effective by the Commission, and (ii) 60 days after the Effective Date, neither the Company nor any subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents. Notwithstanding the foregoing, this Section 8.8 shall not apply in respect of an Exempt Issuance or an Exempt Filing.

(b) From the date hereof until 180 days after the Effective Date, the Company shall not enter into a Variable Rate Transaction.

8.9 **Legend Removal**. The Company shall, at its sole expense, upon appropriate notice from any Purchaser stating that Registrable Securities have been sold pursuant to an effective Secondary Registration Statement, under Rule 144, or any other exemption from the registration requirements under the Securities Act, within the Standard Settlement Period of such notice if such notice is received before 5:00 p.m. on a Business Day (and if such notice is received after 5:00 p.m. Eastern time on a Business Day, within the Standard Settlement Period from the following Business Day), cause its transfer agent to timely prepare and deliver certificates or book-entry shares representing the Shares and Warrant Shares to be delivered to a transferee pursuant to such sale, which certificates or book-entry shares shall be free of any restrictive legends and in such denominations and registered in such names as such Purchaser may request. Further, the Company shall, at its sole expense, cause its legal counsel or other counsel satisfactory to the transfer agent: (i) while the Secondary Registration Statement is effective, to issue to the transfer agent a "blanket" legal opinion to allow sales without restriction pursuant to the effective Secondary Registration Statement, and (ii) provide all other opinions as may reasonably be required by the transfer agent in connection with the removal of legends. A Purchaser may request that the Company remove, and the Company agrees to authorize the removal of, any legend from such Securities, following the delivery by a Purchaser to the Company or the Company's transfer agent of either a legended certificate representing such Securities or, if the Securities are issued in book-entry form, a written request for legend removal: (i) following any sale of such Securities pursuant to Rule 144 or any other applicable exemption from the registration requirements under the Securities Act, or (ii) following the time that the Secondary Registration Statement is declared effective. If a legend removal request is made pursuant to the foregoing, the Company will, no later than the Standard Settlement Period following the delivery by a Purchaser to the Company or the Company's transfer agent of a legended certificate representing such Securities (or a request for legend removal, in the case of Securities issued in book-entry form), deliver or cause to be delivered to such Purchaser a certificate representing such Securities that is free from all restrictive legends or an equivalent book-entry position, as requested by the Purchaser. Certificates for Securities free from all restrictive legends may be transmitted by the Company's transfer agent to a Purchaser by crediting the account of the Purchaser's prime broker with the Depository Trust Company ("***DTC***") as directed by such Purchaser. The Company warrants that the Securities shall otherwise be freely transferable on the books and records of the Company as and to the extent provided in this Agreement. If a Purchaser effects a transfer of the Securities in accordance with Section 5.11, the Company shall permit the transfer and shall promptly instruct its transfer agent to issue one or more certificates or credit shares to the applicable balance accounts at DTC in such name and in such denominations as specified by such Purchaser to effect such transfer. Each Purchaser hereby agrees that the removal of the restrictive legend pursuant to this Section 8.9 is predicated upon the Company's reliance that such Purchaser will sell any such Securities pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and such Purchaser shall deliver a certificate reasonably satisfactory to the Company to the foregoing effect. Prior to the Company and its transfer agent agreeing to a form of representation letter to be given in connection with any legend removal opinion, the Company shall allow each Purchaser to review such form and shall cooperate, reasonably and in good faith, and accept reasonable comments thereto from the Purchasers; and provided, further, that in no event shall the Purchaser be required to agree to indemnify, defend or hold harmless any Person.

8.10 **Use of Proceeds**. The Company shall use the net proceeds from the sale of the Securities hereunder for fund research and development of its clinical-stage product candidate, neflamapimod, working capital and general corporate purposes.

SECTION 9. NOTICES.

All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed facsimile or electronic mail, or mailed by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, and shall be deemed given when so sent in the case of facsimile or electronic mail transmission, or when so received in the case of mail or courier, and addressed as follows:

(a) if to the Company, to:

CervoMed Inc.
20 Park Plaza, Suite 424
Boston, MA 02116
Attn: John Alam, MD
Email: jj.alam@cervomed.com

with a copy to (which shall not constitute notice):

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, MA 02111
Attn: William C. Hicks; Jason S. McCaffrey
Email: WCHicks@mintz.com; JSMccaffrey@mintz.com

or to such other Person at such other place as the Company shall designate to the Purchasers in writing; and

(b) if to the Purchasers, to the applicable address set forth on such Purchaser's signature page hereto or to such other Person at such other place as the Purchasers shall designate to the Company in writing.

SECTION 10. MISCELLANEOUS.

10.1 **Waivers and Amendments.** Neither this Agreement nor any provision hereof may be changed, waived, discharged, terminated, modified or amended except upon the written consent of the Company and, if prior to the Closing, Purchasers that have subscribed for at least 50.1% of the Securities to be issued hereunder, and, if after the Closing, Purchasers holding at least 50.1% of the Securities issued hereunder and then held by all Purchasers, in the case of any change, discharge, termination, modification, or of the party hereto against whom the waiver is to be effective, in the case of a waiver, provided that (a) if any amendment or waiver disproportionately and adversely affects a Purchaser (or a subset of Purchasers) in any material respect, the consent of such disproportionately affected Purchaser (or each Purchaser within such subset of Purchasers) shall also be required and (b) the consent of each Purchaser shall be required for any change in the Purchase Price, any change in the type of security to be issued to Purchasers at Closing, or the amendment, modification or waiver of this Section 10.1, of Section 10.14, of Section 6, or of any of the closing conditions set forth in Sections 3.2(b)(i), 3.2(b)(iii) or 3.2(b)(v). No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing wavier in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. The failure of any party at any time to require another party's performance of any obligation under this Agreement shall not affect the right subsequently to require performance of that obligation.

10.2 **Headings; Interpretation.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement. The terms "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not to any particular provision of this Agreement. Except when used together with the word "either" or otherwise for the purpose of identifying mutually exclusive alternatives, the term "or" has the inclusive meaning represented by the phrase "and/or." All references in this Agreement to "dollars" or "$" shall mean United States dollars. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The term "including" or "includes" means "including without limitation" or "includes without limitation."

10.3 **Severability.** In case any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

10.4 **Survival.** The representations and warranties contained herein shall survive the Closing and the delivery of the Securities. The agreements and covenants contained herein shall survive for the applicable statute of limitations.

10.5 **Governing Law; Jurisdiction.** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to its or any other jurisdiction's choice of law rules. Any and all disputes arising out of, concerning, or related to this Agreement, or to the interpretation, performance, breach or termination thereof shall be referred to and resolved by the federal courts located in New York, New York or, to the extent no such court does not have subject matter jurisdiction, the state courts of the State of New York located in New York, New York (the "***Specified Courts***"). Each of the parties hereto irrevocably and unconditionally submits to the exclusive jurisdiction of the Specified Courts, waives any objection to the laying of venue of any suit, action or proceeding brought in such courts and waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

10.6 **Counterparts.** This Agreement may be executed in counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute but one instrument, and shall become effective when one or more counterparts have been signed by each party hereto and delivered to the other party. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

10.7 **Successors and Assigns.** Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto. None of the Purchasers may assign this Agreement or any rights or obligations hereunder, in whole or in part, without the prior written consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that a Purchaser may assign its rights and delegate its duties hereunder in whole or in part to an Affiliate or to a third party acquiring some or all of the Securities in a transaction complying with applicable securities laws without the prior written consent of the Company, provided such assignee agrees in writing to be bound by the provisions hereof that apply to Purchasers. The Company may not assign this Agreement or any rights or obligations hereunder, in whole or in part, without the prior written consent of all Purchasers. Without limiting the generality of the foregoing, in the event that the Company is a party to a merger, consolidation, share exchange or similar business combination transaction in which the Common Stock is converted into the equity securities of another Person, from and after the effective time of such transaction, such Person shall, by virtue of such transaction, be deemed to have assumed the obligations of the Company hereunder, the term "Company" shall be deemed to refer to such Person and the term "Units," "Shares", "Series A Warrants," "Pre-Funded Warrants", or "Warrant Shares" shall be deemed to refer to the securities received by the Purchasers in exchange therefor in connection with such transaction. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective permitted successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

10.8 **No Third-Party Beneficiaries.** This Agreement is intended for the benefit of the parties hereto and the Placement Agents and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 6.3 and this Section 10.8. Notwithstanding the foregoing, the Placement Agents shall be the third-party beneficiaries of the representations and warranties of the Company in Section 4 of this Agreement and the representations and warranties of the Purchasers in Section 5 of this Agreement. The parties further agree that the Placement Agents may rely on or, if the Placement Agents so request, be specifically named as an addressee of, the legal opinion to be delivered pursuant to this Agreement.

10.9 **Entire Agreement.** This Agreement and the other documents and instruments delivered pursuant hereto or thereto, including the exhibits and schedules hereto or thereto, constitute the full and entire understanding and agreement between the parties hereto with regard to the subjects hereof and thereof and supersede all prior agreements and understandings, both oral and written, between the parties with respect to the subject matter hereof and thereof, *provided*, that any confidentiality agreement that the Company and any Purchaser may have entered into in contemplation of potentially entering into this Agreement, shall survive in accordance with its terms and provisions.

10.10 **Independent Nature of Purchasers' Obligations and Rights.** The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser under this Agreement. The decision of each Purchaser to purchase Units pursuant to this Agreement has been made by such Purchaser independently of any other Purchaser. Nothing contained herein and no action taken by any Purchaser pursuant thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group (within the meaning of Section 13(d) of the Exchange Act or otherwise), or are deemed affiliates (as such term is defined under the Exchange Act) with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser shall be entitled to independently protect and enforce its rights, including the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose. Each Purchaser acknowledges (i) that it is not relying upon any Person other than the Company and its officers and directors, in making its investment or decision to invest in the Company and (ii) no other Purchaser has acted as agent for such Purchaser in connection with making its investment hereunder and that no Purchaser will be acting as agent of such Purchaser in connection with monitoring its investment in the Securities or enforcing its rights hereunder. Each Purchaser agrees that no Purchaser nor the respective controlling persons, officers, directors, partners, agents, or employees of any Purchaser shall be liable to any other Purchaser for any action heretofore or hereafter taken or omitted to be taken by any of them in connection with the purchase of the Securities. The Company acknowledges that each of the Purchasers has been provided with the same Agreement for the purpose of closing a transaction with multiple purchasers and not because it was required or requested to do so by any Purchaser. It is expressly understood that each provision contained in this Agreement is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

10.11 **Payment of Fees and Expenses.** Except as otherwise provided herein or in the other documents or instruments contemplated hereby, each of the Company and the Purchasers shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

10.12 **Further Actions.** Each party hereto agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

10.13 **Securities Law Disclosure.** By no later than 9:00 A.M., New York City time, on the Trading Day immediately following the Effective Date (provided that, if this Agreement is executed between midnight and 9:00 A.M., New York City time on any Trading Day, no later than 9:01 A.M. on the Effective Date), the Company shall issue a press release and/or file a Current Report on Form 8-K with the Commission (the "***Disclosure Document***") disclosing all material terms of the transactions contemplated by this Agreement; *provided*, that each of the Purchasers and Placement Agents shall be given a reasonable opportunity to review and comment on the disclosure contained in the Disclosure Document prior to issuance or filing. In addition, unless it has already done so by filing the Disclosure Document, on or before the fourth (4th) Business Day following the Effective Date, the Company shall file a Current Report on Form 8-K with the Commission disclosing all material terms of the transactions contemplated by this Agreement. From and after the issuance of the Disclosure Document, no Purchaser shall be in possession of any material non-public information received from the Company or from any other representative of the Company in connection with the transactions contemplated by this Agreement, except in the case of information that may have been provided pursuant to any confidentiality agreement between the Company and a Purchaser or agreement between the Placement Agents and such Purchaser. Except for the Disclosure Document and the Current Report on Form 8-K contemplated by this Section 10.13, all public announcements regarding this Agreement shall be issued only in accordance with Section 10.15.

10.14 **Termination.** This Agreement (i) shall be terminated automatically if the Closing has not been consummated on or prior to the fifth Business Day from the Effective Date, or (ii) may be terminated by a Purchaser (with respect to itself) if any of the conditions set forth in Section 3.2(a) or Section 3.2(b) shall have become incapable of fulfillment, and shall not have been waived by such Purchaser, *provided, however*, that no such termination will affect the right of any party to sue for any breach by the other party (or parties), and, upon such termination pursuant to this Section 10.14, any purchase price wired to the Company by a Purchaser shall be promptly returned to the Purchaser, but in no event later than the first Trading Day following such termination.

10.15 **Public Announcement.** The Company shall not publicly disclose the name of any Purchaser or investment adviser of any Purchaser, or include the name of any Purchaser or an Affiliate of any Purchaser without the prior written consent of such Purchaser (i) in any press release or marketing materials or (ii) in any filing with the Commission or any regulatory agency or Trading Market, except as required by U.S. federal securities law (A) in connection with any Secondary Registration Statement contemplated by this Agreement and (B) to the extent such disclosure is required by law, request of the Commission's staff or Trading Market regulations, in which case the Company shall provide the Purchasers with prior written notice of and an opportunity to review such disclosure permitted under this subclause (ii).

10.16 **Placement Agents.** The Company agrees that the Placement Agents, their respective affiliates and their respective representatives shall be entitled to (1) rely on, and shall be protected in acting upon, any certificate, instrument, opinion, notice, letter or any other document or security delivered to any Placement Agent or any Purchaser by or on behalf of the Company, and (2) be indemnified by the Company for acting as a Placement Agent in accordance with the indemnification provisions set forth in the Placement Agent Agreement.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

COMPANY:

CERVOMED INC.

By: /s/ John Alam, M.D.
Name: John Alam, M.D.
Title: Chief Executive Officer

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASER:

RA CAPITAL HEALTHCARE FUND, L.P.

By: RA Capital Healthcare Fund GP, LLC
Its: General Partner

By: /s/ Peter Kolchinsky
Name: Peter Kolchinsky
Title: Manager

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASER:

SPECIAL SITUATIONS FUND III QP, L.P.

By: /s/ David Greenhouse
Name: David Greenhouse
Title: Managing Partner

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASER:

SPECIAL SITUATIONS CAYMAN FUND, L.P.

By: /s/ David Greenhouse
Name: David Greenhouse
Title: Managing Partner

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASER:

SPECIAL SITUATIONS LIFE SCIENCES FUND, L.P.

By: /s/ David Greenhouse
David Greenhouse
Managing Partner

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASER:

ARMISTICE CAPITAL MASTER FUND LTD.

By: /s/ Steven Boyd
Name: Steven Boyd
Title: CIO of Armistice Capital, LLC, the Investment Manager

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASER:

SOLEUS CAPITAL MASTER FUND, L.P.

By: Soleus Capital, LLC, as general partner

By: /s/ Steven Musumeci
Name: Steven Musumeci
Title: COO

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

SCHEDULE A

Purchasers

Purchaser Name and Address	Number of Units	Number of Shares	Number of Pre-Funded Warrants	Number of Series A Warrants	Aggregate Purchase Price of Securities
RA Capital Healthcare Fund, L.P.	1,266,143	817,120	449,023	1,266,143	$ 24,999,544.51
Armistice Capital Master Fund Ltd.	734,363	734,363	-	734,363	$ 14,499,997.44
Special Situations Life Sciences Fund, L.P.	101,291	101,291	-	101,291	$ 1,999,990.80
Special Situations Cayman Fund, L.P.	68,748	68,748	-	68,748	$ 1,357,429.26
Special Situations Fund III QP, L.P.	235,126	235,126	-	235,126	$ 4,642,562.87
Soleus Capital Master Fund, L.P.	126,614	126,614	-	126,614	$ 2,499,993.43
Total	**2,532,285**	**2,083,262**	**449,023**	**2,532,285**	**49,999,518.30**

SCHEDULE B

Company Wire Instructions

SCHEDULE C

Executive Officers:
John Alam, M.D. (also a Director)
Robert J. Cobuzzi, Jr., Ph.D. (also a Director)
William Tanner, Ph.D.
Kelly Blackburn
William Elder

Directors:
Joshua Boger, Ph.D.
Sylvie Gregoire, PharmD
Jeff Poulton
Jane H. Hollingsworth
Frank Zavrl
Marwan Sabbagh, M.D.

EXHIBIT A

[Form of Pre-Funded Warrant]

EXHIBIT B

[Form of Series A Warrant]

EXHIBIT C

D&O Lock-up

LOCK-UP AGREEMENT

March 28, 2024

Morgan Stanley & Co. LLC
Canaccord Genuity LLC

c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, NY 10036

c/o Canaccord Genuity LLC
1 Post Office Square, Suite 3000
Boston, Massachusetts 02109

Ladies and Gentlemen:

The undersigned understands that CervoMed Inc., a Delaware corporation (the "**Company**"), has entered into an agreement with Morgan Stanley & Co. LLC ("**Morgan Stanley**") and Canaccord Genuity LLC ("**Canaccord**") as its placement agents (together, the "**Placement Agents**") in connection with a proposed private placement (the "**Placement**") of the Company's equity and equity-linked securities (together, the "**Securities**"), which may include shares of common stock, par value $0.001 per share of the Company (the "**Common Stock**") and warrants exercisable for shares of the Company's Common Stock.

In consideration of the Placement Agents' agreement to place the Securities, and for other good and valuable consideration receipt of which is hereby acknowledged, the undersigned hereby agrees that, without the prior written consent of each of the Placement Agents, it will not, and will not publicly disclose an intention to, during the period commencing on the date hereof and ending 15 days after the effectiveness of the Resale Registration Statement, as that term is defined in the definitive securities purchase agreement (the "**Securities Purchase Agreement**") in connection with the Placement (the "**Restricted Period**") , (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock beneficially owned (as such term is used in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for shares of Common Stock (collectively, the "**Lock-Up Shares**") or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing sentence shall not apply to:

(a) if the undersigned is a natural person, transfers of Lock-Up Shares (i) to any natural person related to the undersigned by blood or adoption who is an immediate family member of the undersigned, or to a trust for the benefit of the undersigned or any member of the undersigned's immediate family for estate planning purposes, or to the undersigned's estate, following the death of the undersigned, by will, intestacy, or other operation of law, or as a bona fide gift to a charitable organization or to any partnership, corporation or limited liability company which is controlled by the undersigned and/or by any such member of the undersigned's immediate family or (ii) by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement;

(b) if the undersigned is a corporation, partnership or other business entity, transfers of Lock-Up Shares to another corporation, partnership or other business entity that is an affiliate (as defined under Rule 12b-2 promulgated under the Exchange Act) of the undersigned or as a distribution or dividend to equity holders (including, without limitation, general or limited partners and members) of the undersigned (including upon the liquidation and dissolution of the undersigned pursuant to a plan of liquidation approved by the undersigned's equity holders), or as a bona fide gift to a charitable organization;

(c) if the undersigned is a trust, transfers of Lock-Up Shares to any grantors or beneficiaries of the trust;

(d) exercise an option to purchase shares of Common Stock and any related transfer of shares of Common Stock to the Company for the purpose of paying the exercise price of such options as a result of the exercise of such options; *provided*, that for the avoidance of doubt, the underlying shares of Common Stock shall continue to be subject to the restrictions on transfer set forth in this agreement until the Restricted Period;

(e) facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, *provided* that (i) such plan does not provide for the transfer of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period; and

(f) transfer its Lock-Up Shares pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of Company's capital stock involving a Change of Control (as defined below) of Company; *provided* that Lock-Up Shares subject to this agreement that are not so transferred, sold, tendered or otherwise disposed of remain subject to this agreement; and *provided, further,* that in the event that such tender offer, merger, consolidation or other such transaction is not completed, the Lock-Up Shares shall remain subject to the restrictions contained in this agreement;

and *provided* that (1) in the case of that with respect to any transfer or distribution pursuant to (a)(i), (b), (c) and (d) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of Common Stock, shall be required or shall be voluntarily made during the Restricted Period, (2) any filing or announcement by the Company or the undersigned relating to a transfer or distribution under clauses (a)(ii) and (f) above shall note the applicable circumstances that cause such clause to apply and explain that the filing or announcement relates solely to transfers or distributions falling within the category described in the relevant clause), and (3) except with respect to Section (e) and (f) above, it shall be a condition to the transfer or distribution that the transferee or distributee executes an agreement, in the form of this agreement, stating that the transferee or distributee is receiving and holding such Lock-Up Shares subject to the provisions of such agreement until the Restricted Period. For purposes of this agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin and "Change of Control" shall mean the consummation of any bona fide third party tender offer, merger, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 90% of total voting power of the voting stock of the Company.

In addition, the undersigned agrees that, without the prior written consent of each of the Placement Agents, it will not, during the Restricted Period, make any demand for or exercise any right with respect to, the registration of any Lock-Up Shares. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's Lock-Up Shares except in compliance with the foregoing restrictions.

The undersigned understands that the Company and the Placement Agents are relying upon this agreement in proceeding toward consummation of the Placement. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

The undersigned acknowledges and agrees that the Placement Agents have not provided any recommendation or investment advice nor have the Placement Agents solicited any action from the undersigned with respect to the Placement or this agreement and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate. The undersigned further acknowledges and agrees that, although the Placement Agents may provide certain Regulation Best Interest and Form CRS disclosures or other related documentation to you in connection with the Placement and this agreement, the Placement Agents are not making a recommendation to you to participate in the Placement or sell any Shares at the price determined in the Placement, and nothing set forth in such disclosures, documentation or this agreement is intended to suggest that the Placement Agents are making any such recommendation.

Whether or not the Placement actually occurs depends on a number of factors, including market conditions. Any Placement will only be made pursuant to a Securities Purchase Agreement, the terms of which are subject to negotiation between the Company and each purchaser named therein.

The undersigned understands that the undersigned shall be released from all obligations under this letter agreement if the Securities Purchase Agreement shall terminate or be terminated prior to the closing of the Placement.

This agreement shall be governed by and construed in accordance with the laws of the State of New York.

Very truly yours,

_____

(Name)

_____

(Address)

EXHIBIT D

Investor Representation Letter

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the use in this Registration Statement on Form S-1 of CervoMed Inc. of our report dated March 29, 2024, relating to the consolidated financial statements of CervoMed Inc. and its subsidiaries, appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to our firm under the heading “Experts” in such Prospectus.

/s/ RSM US LLP

Boston, Massachusetts
May 10, 2024

Exhibit 107

Calculation of Filing Fee Tables
FORM S-1

(Form Type)
CervoMed Inc.

(Exact Name of Registrant as Specified in its Charter)
Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1) (2)	Proposed Maximum Offering Price Per Unit(3)	Maximum Aggregate Offering Price(3)	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Common Stock, par value $0.0001 per share	457(c)	5,064,570	$23.96	$121,329,624.42	$0.00014760	$17,908.25
		Total Offering Amounts						$17,908.25
		Total Fees Previously Paid						--
		Total Fee Offsets						--
		Net Fee Due						$17,908.25

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), this registration statement also covers such an indeterminate amount of shares of common stock of the registrant as may become issuable to prevent dilution resulting from stock splits, stock dividends and similar events.

(2) The amount registered consists of (i) 2,083,262 shares of common stock of the registrant held by selling stockholders, (ii) 449,023 shares of common stock of the registrant issuable upon the exercise of 449,023 pre-funded warrants of the registrant held by a selling stockholder, and (iii) 2,532,285 shares of common stock of the registrant issuable upon the exercise of Series A warrants held by the selling stockholders.

(3) Estimated solely for the purpose of calculating the registration fee, based on the average of the high and low prices of the shares of common stock of the registrant on The Nasdaq Capital Market on May 3, 2024 (such date being within five business days of the date that this registration statement was first filed with the U.S. Securities and Exchange Commission, in accordance with Rule 457(c) under the Securities Act).