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

FORM 10-K

(Mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission file number: 001-37942

CervoMed Inc.

(Exact Name of Registrant as specified in its Charter)

Delaware	**30-0645032**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No)
20 Park Plaza, Suite 424, Boston, Massachusetts	**02116**
(Address of Principal Executive Offices)	(Zip Code)

(617) 744-4400
(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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 to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicated by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant’s common stock beneficially owned by non-affiliates of the registrant, calculated based upon the closing sale price of the common stock as quoted by the Nasdaq Capital Market on June 30, 2025 (the last business day of the registrant’s second fiscal quarter), was approximately $39.9 million.

As of March 11, 2026, 9,258,719 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated by reference from the Registrant’s Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

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INTRODUCTORY NOTES

Note Regarding Company References and Other Defined Terms

Unless the context otherwise requires, all references in this Annual Report to (i) "CervoMed," the "Company," "we," "our," or "us," refer to the business of CervoMed Inc. for all dates and periods subsequent to (and including) August 16, 2023 and to the business of EIP Pharma, Inc. ("EIP"), our wholly-owned subsidiary and the accounting acquirer in the Merger (as defined below) for all dates and periods prior to August 16, 2023 and (ii) "common stock" refer to our common stock, par value $0.001 per share.

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

Term	Definition
2015 Equity Plan	CervoMed Inc. 2015 Equity Incentive Plan, as amended
2018 Plan	CervoMed Inc. 2018 Employee, Director and Consultant Equity Incentive Plan, as amended
2020 Notes	the previously outstanding convertible promissory notes of EIP, dated as of December 4, 2020, as amended
2021 Notes	the previously outstanding convertible promissory notes of EIP, dated as of December 10, 2021, as amended
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
2025 Equity Plan	CervoMed Inc. 2025 Equity Incentive Plan
401(k) Plan	CervoMed Inc. 401(k) Defined Contribution Plan
AD	Alzheimer's Disease
Annual Report	this Annual Report on Form 10-K
AAIC	Alzheimer's Association International Conference
ACA	Affordable Care Act and the Healthcare and Education Reconciliation Act
ADCS-CGIC	the Alzheimer's Disease Cooperative Study — Clinical Global Impression of Change
AI	artificial intelligence
AIA	America Invents Act
AKS	anti-kickback statute
ALS	amyotrophic lateral sclerosis
ALT	alanine aminotransferase
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
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
AST	aspartate aminotransferase
ASU	Accounting Standards Update
Batch A	the batch of neflamapimod DP capsules manufactured in October 2020 and administered for the Randomized Phase of the RewinD-LB Trial and a portion of the Extension
Batch B	the batch of neflamapimod DP capsules manufactured in March 2023 and administered for the majority of the RewinD-LB Trial Extension
Bayh-Dole Act	Bayh-Dole Act of 1980
BID	twice daily
BFC	basal forebrain cholinergic
Board	our board of directors
CARES Act	Coronavirus Aid, Relief, and Economic Security Act

CCPA	the California Consumer Privacy Act
CDMO	contract development and manufacturing organization
CDR-SB	Clinical Dementia Rating Sum of Boxes test
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 US Centers for Medicare & Medicaid Services
CNPV	Commissioner's National Priority Voucher
CNS	central nervous system
Code	the US Internal Revenue Code of 1986, as amended
CODM	chief operating decision maker
CPRA	the California Privacy Rights Act
CREATES Act	the Creating and Restoring Equal Access to Equivalent Samples Act of 2019
CRL	Complete Response Letter
CRO	contract research organization
DGCL	Delaware General Corporation Law
DGM	deep grey matter
DLB	dementia with Lewy bodies
DLB without AD co-pathology	DLB without concomitant AD-related pathology. May also be referred to as "pure" DLB.
DNP	the FDA’s Division of Neurology Products
DP	drug product
DS	drug substance
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	EIP Pharma, Inc., our wholly-owned subsidiary
EIP Common Stock	the common stock, par value $0.001, of EIP issued and outstanding prior to the Merger
EMA	European Medicines Agency
EOAD	Early Onset Alzheimer’s Disease
EOT	end of treatment
ERISA	the Employment Retirement Income Security Act
Exchange Act	Securities Exchange Act of 1934, as amended
EXPERTS-ALS	a randomized, multicenter, open-label, multi-arm trial that evaluates investigational medicines for the treatment of ALS, funded by the UK National Institute for Health and Care Research and leading motor neuron disease charities
Extension or Extension Phase	with respect to the RewinD-LB Trial, the 32-week open-label extension phase of the trial from which 16-week results were reported in March 2025
FASB	Financial Accounting Standards Board
FCA	False Claims Act
FCPA	the Foreign Corrupt Practices Act
FDA	US Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FDIC	Federal Deposit Insurance Corporation
FTC	Federal Trade Commission
FTD	frontotemporal disorders
GCP	good clinical practices
GDPR	European Union General Data Protection Regulation
GFAP	glial fibrillary acidic protein

GLP	good laboratory practice
HIPAA	the Health Insurance Portability and Accountability of Act of 1996
IEEPA	International Emergency Economic Powers Act
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
MAPK	mitogen-activated protein kinase
MCI	mild cognitive impairment
Merger	the merger of Dawn Merger Sub Inc. with and into EIP, with EIP surviving the Merger as a wholly-owned subsidiary of the Company, pursuant to the Merger Agreement, completed on August 16, 2023
Merger Agreement	the Agreement and Plan of Merger, dated March 30, 2023, by and among Diffusion Pharmaceuticals Inc., Dawn Merger Sub Inc., a wholly-owned subsidiary of Diffusion and EIP
MMRM	mixed-effects model for repeated measures
MoCA	Montreal Cognitive Assessment
MRI	magnetic resonance imaging
MSN	medial septal nucleus
Nasdaq	Nasdaq Stock Market, LLC
NbM	Nucleus basalis of Meynert, the largest cluster of cholinergic neurons in the basal forebrain
NCE	new chemical entity
NDA	new drug application
NfL	neurofilament light chain protein
nfvPPA	non-fluent variant primary progressive aphasia
NGF	nerve growth factor
NIA	the National Institute on Aging of the National Institutes of Health
NIA Grant	the $21.3 million grant awarded to us by the NIA to support the RewinD-LB Trial, $21.0 million of which was awarded in January 2023 and an additional $0.3 million of which was awarded in August 2024
NIH	National Institutes of Health
NOL	net operating loss
NTB	Neuropsychological Test Battery
NYSE	New York Stock Exchange
OBBBA	H.R. 1, formerly known as the One Big Beautiful Bill Act of 2025, enacted on July 4, 2025
p38α	p38 mitogen-activated protein kinase alpha
PBM	pharmacy benefit manger
PD	Parkinson's disease
PDAB	prescription drug affordability board
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act, as amended
PK	pharmacokinetics
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
Proxy Statement	the definitive proxy statement on Schedule 14A for our 2025 Annual Meeting of Stockholders
ptau181	plasma phosphorylated tau at position 181
RA	rheumatoid arthritis
Randomized Phase	with respect to the RewinD-LB Trial, the initial, randomized, 16-week double-blind, placebo controlled phase of the trial from which topline results were reported in December 2024
RAS	Recovery After Stroke
Regulation S-K	Regulation S-K promulgated under the Securities Act
REMS	Risk Evaluation and Mitigation Strategy
RESTORE Trial	our ongoing Phase 2a clinical trial evaluating neflamapimod for the treatment of patients recovering from ischemic stroke, which we initiated in the second quarter of 2025
RewinD-LB Trial	our Phase 2b clinical trial evaluating neflamapimod for the treatment of patients with DLB, from which we announced final results in October 2025
RLD	reference-listed drug
ROU	right-of-use
SAB	scientific advisory board
SAE	serious adverse events
Sales Agreement	Sales Agreement, dated May 12, 2025, by and between the Company and Leerink Partners, LLC
SAP	statistical analysis plan
SEC	US 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
TEAE	treatment-emergent adverse event
TID	three times daily
TUG	Timed Up and Go test
UK	United Kingdom
UPL	upper payment limit
US	United States of America
US GAAP	US generally accepted accounting principles
USPTO	US 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

Note Regarding Forward-Looking Statements

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

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

- our cash balances, our ability to obtain additional financing in the future, and our ability to continue as a going concern;
- the success and timing of our ongoing and planned clinical trials and nonclinical studies, including our ability to enroll participants in our studies at anticipated rates, our ability to manufacture an adequate amount of drug supply for our studies, and changes to our drug candidates' formulations;
- obtaining and maintaining intellectual property protection for our current or future product candidates and our proprietary technology;
- the performance of third parties, including CROs, CDMOs, manufacturers, suppliers, and outside consultants, to whom we outsource certain operations, 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 IT systems and infrastructure;

- recently enacted and future legislation related to the healthcare system;
- other regulatory developments in the US, 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 Annual Report. Accordingly, we cannot assure you that the forward-looking statements contained in this Annual Report will prove to be accurate or that any such inaccuracy will not be material. You should also understand that it is not possible to predict or identify all such factors, and you should not consider any such list to be a complete set of all potential risks or uncertainties. In light of the foregoing and the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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

Note Regarding Trademarks, Trade Names, and Service Marks

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

Note Regarding Data from Clinical Trials and Nonclinical Studies

All analyses reported from clinical trials and nonclinical studies are exploratory in nature. P-values and 95% confidence intervals are reported to provide a measure of the probability that any differences identified between the samples are due to chance. All ptau181 measurements for the RewinD-LB Trial are reported based on the Quanterix v2.1 assay scale, which utilizes a different standard than the prior version of such assay (v2.0) on which ptau181 measures for our AscenD-LB Trial are reported. Quantitative values on the v2.1 scale are approximately ten-fold higher than corresponding values on the v2.0 scale related to the standard that is used for the assay.

PART I

ITEM 1. BUSINESS

Overview

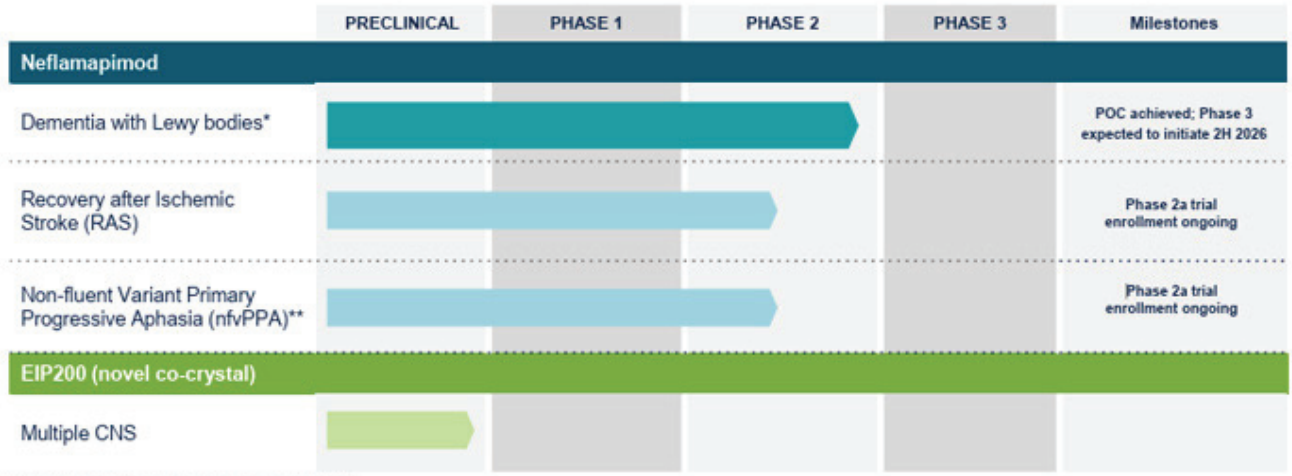
We are a clinical-stage biotechnology company developing treatments for age-related brain disorders. Our lead drug candidate, neflamapimod, is an investigational, orally administered small-molecule drug that readily crosses the blood brain barrier and selectively inhibits the enzyme p38α, a key driver of neuroinflammation and synaptic dysfunction. By targeting the critical disease processes underlying degenerative disorders of the brain, neflamapimod has the potential to reverse synaptic dysfunction, improve neuron health, and slow or prevent disease progression. Neflamapimod is currently in clinical development for the treatment of DLB, our lead indication, as well as nfvPPA, RAS, and ALS.

Our novel approach focuses on reducing the impact of neuroinflammation, which we believe is a key factor in the manifestation of degenerative diseases of the brain. Chronic activation of p38α in the brains of people with certain neurodegenerative diseases is believed to impair how neurons communicate through synapses. This synaptic dysfunction leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in irreversible 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 many major neurodegenerative disorders, including DLB, initially involves a protracted period of reversible functional loss, particularly with respect to the synapses. We believe that inhibiting p38α activity in the brain has the potential to reverse the clinical progression observed in the early stages of certain neurodegenerative diseases, as well as slow further progression by delaying permanent synaptic dysfunction and neuron death, by interfering with key pathogenic drivers of disease.

We believe we are a leader in the industry in developing a treatment for DLB, a disease with no approved therapies in the US or European Union, despite being the second most common progressive dementia. Neflamapimod is the only clinical drug candidate that, to our knowledge, has shown statistically significant improvements on clinical endpoints and a biomarker of neurodegeneration in both a Phase 2a and Phase 2b clinical trial. Differentiating our approach from potential competitors, we believe we are also the only company specifically targeting the treatment of DLB patients without AD co-pathology. While DLB patients with AD co-pathology generally have significant, irreversible neuronal loss, DLB without AD co-pathology is primarily a disease of functional deficits of synapses that we believe is more treatable. We believe if neflamapimod is given in the early stages of certain degenerative diseases of the brain like DLB without AD co-pathology, it may reverse synaptic dysfunction, improve neuron health and function, and slow further progression by delaying synaptic dysfunction and neuronal death. We believe this approach enhances the alignment of our development path with neflamapimod's mechanism of action, reduces the heterogeneity of our target patient population, and provides the opportunity to demonstrate heightened clinical effect in shorter duration trials.

Our Pipeline

Set forth below is a table presenting our clinical pipeline:



Worldwide commercial rights across programs
*Received FDA Fast Track designation
**Sub-type of Frontotemporal Disorders, for which neflamapimod has received FDA Orphan Drug designation

Anticipated Milestones

Set forth below are our anticipated clinical development milestones during the next 12 months, subject to, among other things, available funding:

Anticipated Milestones	
2Q26	Complete enrollment in Phase 2a clinical trial in nfvPPA
Mid-2026	Complete enrollment in Phase 2a RESTORE Trial in RAS
Mid-2026	Initial Phase 2a biomarker data in nfvPPA
2H26	Topline Phase 2a clinical data in RAS
2H26	Initial Phase 2a clinical data in nfvPPA
2H26	Initiation of planned Phase 3 trial in DLB
YE26	First patient dosed with neflamapimod in EXPERTS-ALS trial in ALS
1H27	Topline Phase 2a clinical and biomarker data in nfvPPA

Our Strategy

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

The key elements of our strategy are:

- *Capitalize on neflamapimod's unique properties and our differentiated approach to progress the development of neflamapimod for the treatment of age-related brain disorders with high unmet medical need.* Our approach to treating neurodegenerative disorders is highly differentiated, focusing on reducing the impact of neuroinflammation in patients afflicted by diseases primarily of synaptic dysfunction who do not have significant, irreversible neuronal loss. We believe, if approved, the nature of neflamapimod's mechanism of action, combined with the nature and prevalence of these diseases, could significantly improve patients' quality of life and ability to function, reduce caregiver burden and systemic health care costs, and present a significant commercial opportunity in one or more indications.

- *Advance clinical development of neflamapimod as a potential first-in-class treatment for DLB without AD co-pathology, including securing sufficient funding and initiating our planned Phase 3 trial in the second half of 2026, subject to available funding.* During 2025, we announced 16-week and 32-week results from the Extension Phase of our RewinD-LB Trial in which neflamapimod demonstrated significant, durable effects on the trial's primary endpoint (CDR-SB), a key biomarker of neurodegeneration in DLB (plasma GFAP), and secondary endpoints including ADCS-CGIC when target blood concentrations were achieved. These results were even more pronounced in the patient population to be enrolled in our planned Phase 3 trial, which will use more restrictive criteria to exclude patients with AD co-pathology. In November 2025, we announced alignment with the FDA on key aspects of our planned Phase 3 clinical trial of neflamapimod, and we plan to initiate that trial in the second half of 2026, subject to available funding.

- *Advance clinical development of neflamapimod for other disease indications.* Beyond DLB, neflamapimod's mechanism of action provides opportunities for advancement in a range of additional neurologic disorders. During 2025, we initiated Phase 2a clinical trials in nfvPPA and RAS, from which we expect initial biomarker results and topline clinical results in mid-2026 and the second half of 2026, respectively, subject to available funding to continue operations. In addition, in February 2026, we announced that neflamapimod has been selected for inclusion in EXPERTS-ALS, a platform funded by the UK government and leading charities to facilitate rapid testing of potential treatments for ALS to identify promising drug candidates and potentially accelerate their path to regulatory approval. We believe neflamapimod's inclusion in the EXPERTS-ALS platform serves to further validate its mechanism of action and potential in neurodegenerative diseases. We also believe there is strong scientific basis for evaluating neflamapimod in these indications and that differences in the treatment setting and disease processes involved provide development opportunities that are both differentiated from and complementary to our DLB program.

- *Explore strategic collaborations to maximize neflamapimod's potential value, support its development, and expedite commercialization, if approved.* We believe that strategic collaborations may provide opportunities to maximize neflamapimod's potential value for our stockholders and we intend to explore potential strategic collaborations in parallel with our planned clinical development program for neflamapimod, which may include region- or indication-specific partnerships. In addition, 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 would be in North America and/or Europe. In the future, we may seek partners to seek approval and commercialize our products in other regions.

Neflamapimod in Dementia with Lewy Bodies

DLB Background

Significant Disease Burden & High Unmet Medical Need

DLB is the second most common progressive dementia after AD, representing approximately 10-20% of all dementia cases and affecting millions worldwide. The Lewy Body Dementia Association suggest there are more than 700,000 individuals with DLB in each of the US and the European Union, and neuropathology studies suggest true incidence may be significantly higher due to underdiagnosis in current practice. Despite this prevalence, there are currently no approved treatments specifically for DLB in the US or the European Union.

The disease is characterized by progressive dementia and fluctuating cognition (particularly deficits in attention), visual hallucination, motor dysfunction (disturbances in gait and balance), and sleep disturbances. While DLB afflicts fewer total patients than AD, it is arguably a more debilitating disease. 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 average survival for DLB patients (<4 years) was nearly 50% was shorter than the average survival for AD patients (~7 years). The average time progression to severe dementia was also shorter by nearly two years in DLB and, even in the mild-to-moderate stages, the disease burden with respect to quality of life and caregiver burden is greater in DLB than in AD, with deficits occurring in both cognitive and motor function. For example, 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-year median in the AD group. Patients with DLB are also more frequently admitted to general hospitals, are more prone to falls, and utilize inpatient care to a substantially higher degree than patients with AD and the general elderly population.

In sum, DLB 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 approved treatments available for DLB in the US or European Union, so management of DLB focuses on transient relief of symptoms, including its cognitive manifestations and motor components via cholinesterase inhibitors and dopaminergic medications, respectively. Even with these treatments, the cognitive and functional impairments progress rapidly, caregiver burden remains high, and new options are needed for these patients. No prior approaches have been shown to clinically slow neuronal loss or prevent cognitive decline in DLB, and neflamapimod is one of only a handful of drug candidates that have demonstrated positive effects in a Phase 2 clinical trial.

Neflamapimod's Mechanism of Action & Scientific Rationale

Our approach is based on an understanding of the mechanism by which neuroinflammation leads to the initiation and establishment of the neurodegenerative process in DLB. The process of neurodegeneration starts with dysfunction of synapses. 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 neurodegenerative disorders, 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 – specifically, nerve cells producing the neurotransmitter acetylcholine known as cholinergic neurons – plays critical roles in controlling and optimizing a wide range of cognitive, motor, and visual tasks. Synaptic dysfunction in the BFC system is the primary pathogenic driver of disease expression and progression in DLB. In collaborative work we conducted with the New York University Langone Medical Center, and later published in the journal *Nature Communications*, we demonstrated that neflamapimod targets the specific molecular mechanisms underlying BFC dysfunction and degeneration, and may successfully reverse disease progression in the early stages of BFC dysfunction.

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, is the major activator of Rab5. The protein Rab5 is a master regulator of endocytosis and endosomal trafficking. As shown in the figure below, cholinergic degeneration is believed to result from inflammation and various aggregated proteins that lead to aberrant activation of Rab5. This Rab5 activation leads 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 cholinergic neurons in the basal forebrain. As NGF provides support for neuronal health, the resulting loss is then believed to lead to dysfunction, and, eventually, degeneration of cholinergic neurons – which, as noted above, plays a critical role in DLB disease expression – as these neurons' very long fibers make them particularly vulnerable to this pathogenic process.

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

Our Differentiated Approach: DLB Without AD Co-Pathology

Historically, a major challenge in developing effective drug treatments for chronic neurodegenerative diseases has been an inability to demonstrate clinically meaningful improvement in Phase 2 clinical trials of less than six-months in duration. Instead, due to a variety of factors including the nature of many such diseases, particularly AD, demonstrating effectiveness often depends on clinical trial durations of 12-18 months that enroll 1,000 or more participants. Further, prior Phase 2 clinical trial data – often utilizing a different primary endpoint than will be used in Phase 3, such as an indicative biomarker – may not provide as meaningful a predictor of these drug candidates' potential for a successful clinical outcome in Phase 3. Effectively requiring Phase 3 trials to see a clinical effect, late-stage clinical development in these indications is often associated with significant costs, time horizons, and clinical risk. Some incorrectly associate these same challenges with DLB drug development, in part due to the prominence of AD co-pathology in DLB patients.

In contrast, our DLB development program for neflamapimod is focused on the treatment of DLB without AD co-pathology, which we sometimes refer to as "pure DLB." These patients comprise approximately 50% of all DLB patients, with hundreds of thousands of patients diagnosed in the US and millions worldwide. While DLB patients with AD co-pathology have significant, irreversible neuronal loss in the hippocampus, pure DLB is primarily a disease of reversible synaptic dysfunction in the BFC system. Relative to patients with AD co-pathology, these patients have limited neurodegeneration and neuronal loss in the cortical regions of the brain, particularly in the hippocampus. As those neurons are still alive, with successful pharmacological treatment, they can be rescued and the disease process reversed. Importantly, DLB remains a rapidly progressing disease, even in the absence of AD co-pathology, with families and caregivers often reporting seeing patients progress on a weekly or even daily basis.

The core of our differentiated approach sits at the intersection of these two features of pure DLB. The combination of less extensive neuronal loss and fixed clinical deficit, on the one hand, and rapid progression, on the other, provides the opportunity to demonstrate meaningful clinical effects compared to control in as soon as 16 weeks – as we have in our two Phase 2 trials described in more detail below – rather than the 52 weeks or more that is often required in AD trials. This approach was also central to our November 2025 alignment with the FDA on key aspects of our proposed Phase 3 clinical trial of neflamapimod for the treatment of DLB. With the FDA's feedback, and subject to available funding, we plan to initiate a single Phase 3 clinical trial of 32 weeks duration in approximately 300 patients with DLB without AD co-pathology, utilizing the same primary endpoint (mean change in CDR-SB) as our recently completed Phase 2b trial.

We believe that, in contrast to many late-stage trials in other neurodegenerative diseases like AD, this consistency in primary endpoint from Phase 2b has the potential to increase our probability of success in Phase 3, while the ability to demonstrate a clinically meaningful effect with fewer patients and on a shorter timeline allows us to execute towards that outcome with more capital efficiency.

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

The AscenD-LB Trial was an exploratory, Phase 2a clinical trial designed to evaluate the effects of neflamapimod against a range of clinical endpoints. A total of 91 participants were enrolled between October 2019 and March 2020 and randomized to receive neflamapimod capsules at one of two doses (40mg[6] BID or 40mg TID) or matching placebo capsules (randomized 1:1) for 16 weeks. In the primary analysis of the AscenD-LB Trial, which included all participants 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 (as assessed by the TUG test, p=0.044 vs. placebo). In additional analyses, at the higher dose (40mg TID), improvement on NTB was evident as compared to placebo (p=0.049). Encouraging positive trends on the ten-item Neuropsychiatric Inventory were also seen, particularly with respect to visual hallucinations. This primary analysis of the AscenD-LB Trial data showing neflamapimod significantly improved dementia severity and motor function was published in *Nature Communications* in September 2022.

With progress in laboratory testing techniques for blood biomarkers of neurodegeneration during and shortly following completion of the AscenD-LB Trial, additional pre-specified analyses of the AscenD-LB Trial data were conducted to evaluate the results specifically in DLB patients without AD co-pathology, as assessed by plasma ptau181. As shown in the table below, participants without evidence of AD co-pathology had an average higher treatment response (evaluated by Cohen's *d* effect size) compared to the average response in the overall trial population, and demonstrated significant improvement in CDR-SB, cognitive tests of attention, the TUG test, and in a test of recognition memory (International Shopping List Test recognition index), with Cohen's *d* treatment effect sizes indicating, in each case, clinical effects that are moderate-to-large in magnitude (> 0.7). By comparison, cholinesterase inhibitors – the current standard of care in DLB – have Cohen's *d* effect size of approximately 0.3 in the treatment of both DLB and AD. Further, not only was the effect size with 40mg TID neflamapimod treatment comparatively larger, the effect demonstrated was on top of participant's background therapies which, in many cases, included cholinesterase inhibitors.

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

Trial Background and Design

Based on our successes and advances in Phase 2a, we designed our Phase 2b RewinD-LB Trial and, in January 2023, we were awarded a $21.0 million grant from the NIA, and an additional $0.3 million was awarded in August 2024, to fund the majority of the trial's costs. The trial, subsequently initiated in mid-2023, evaluated neflamapimod in 159 participants with DLB and incorporated in its design several important things we learned from the AscenD-LB Trial and our other clinical evaluations of neflamapimod:

- Evaluating only a 40mg TID dosing regimen, as earlier clinical trials in DLB and AD demonstrated that achieving target plasma drug concentrations (which 40mg BID did not do in Phase 2a) was critical to maximizing neflamapimod's effectiveness to date;

- Selecting CDR-SB, increasingly viewed as the gold standard for clinical evaluation of early AD and arguably even more well-suited to DLB's symptomology, as it can detect effects on both cognitive and motor function, as the trial's primary endpoint; and

- Partially enriching the trial's patient population by excluding certain patients with AD co-pathology, as assessed by screening levels of plasma ptau181, a blood biomarker of AD co-pathology.

The RewinD-LB Trial included two distinct parts. The Randomized Phase was a double-blind, placebo-controlled evaluation of neflamapimod administered orally, 40mg TID, randomized with placebo on a one-to-one basis, with a primary analysis after 16 weeks of treatment. Each treatment group included approximately 80 participants diagnosed with DLB by consensus criteria (global CDR = 0.5 or 1.0). To enrich for patients without AD co-pathology, patients with significantly elevated plasma ptau181 at screening (≥ 27.2 pg/ml) were excluded. The second phase of the trial was a 32-week open-label treatment Extension Phase for participants completing the Randomized Phase. The failure of Batch A to achieve target drug concentrations and the pre-planned introduction of Batch B (which did) allowed us to amend the trial's statistical analysis plan in February 2025 – prior to our analysis and announcement of 16-week Extension Phase results in March 2025 – to include a pre-specified analysis of Batch B versus Batch A after both 16- and 32-weeks of treatment during the Extension Phase. Further, although the Extension Phase was open-label, both participants and site personnel were unaware of which batch they were receiving, allowing a controlled comparison of an effective batch of neflamapimod (Batch B, which served as the active arm) against an ineffective batch (Batch A, which served as a control).

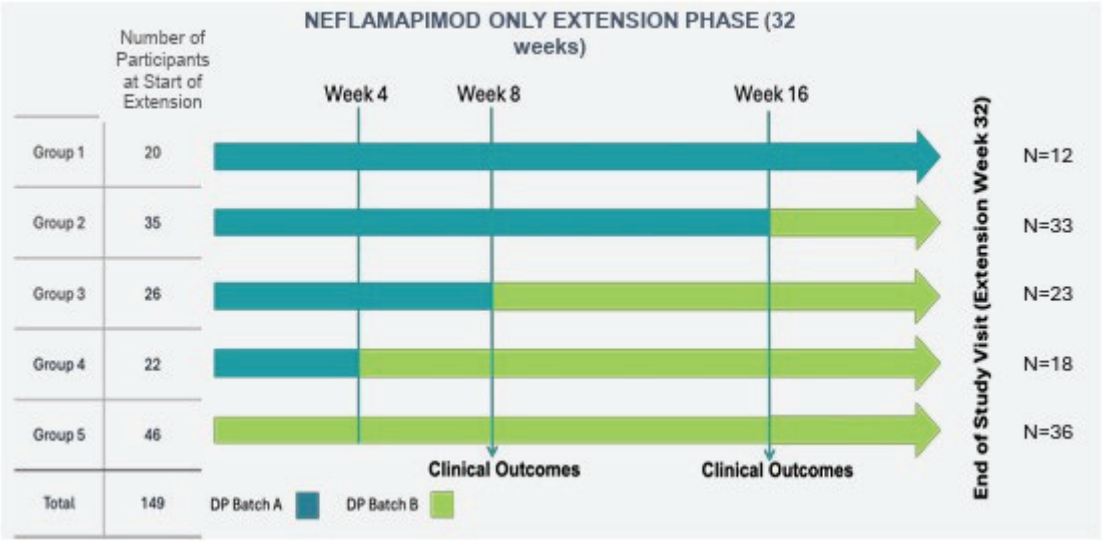
The primary objective of the trial was to demonstrate that neflamapimod, compared with placebo or control, improved dementia severity, as assessed by mean change from baseline to Week 16 in CDR-SB. CDR-SB is designed to assess both cognition and function, and is obtained by clinicians rating the severity of symptoms across six 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 included further evaluation of the safety and tolerability of neflamapimod and treatment effects on (1) global rating of treatment effect, assessed by the ADCS-CGIC, (2) motor function, as assessed by the TUG test, and (3) cognition, assessed by a DLB-specific cognitive test battery. Tertiary endpoints examined 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 as alpha-reactivity evaluated by EEG) and in a sub-set of participants, basal forebrain atrophy assessed by structural MRI.

Randomized Phase Results

In December 2024, we announced topline results from the Randomized Phase of the RewinD-LB Trial. In the Randomized Phase, during which all participants received Batch A, no significant differences were observed between the neflamapimod and placebo treatment groups with respect to CDR-SB or any of the trial's secondary endpoint. However, average trough plasma drug concentrations with Batch A during the Randomized Phase were more than 20% lower than our target concentration level. As described further below under *Alignment with FDA on Planned Phase 3 Trial – Pre-Phase 3 Manufacturing Improvements*, we subsequently determined that the reduction was caused by an unknown, latent property of neflamapimod DS. We are implementing a manufacturing improvement that will address this issue ahead of our planned Phase 3 trial and going forward. However, particularly given the importance of achieving target drug concentrations to maximizing neflamapimod's effectiveness described above, we believe this issue was a primary driver of our failure to see during the Randomized Phase the same positive results with saw with Batch B during the Extension Phase.

Extension Phase Results

Of the 159 participants randomized in the Randomized Phase, 152 completed the Randomized Phase and 149 entered the neflamapimod only Extension Phase. The chart below shows when the pre-planned introduction of Batch B to resupply the Extension Phase occurred for those 149 patients:



In March 2025, we announced that, in the first 16 weeks of the Extension Phase, treatment with Batch B – which, unlike Batch A, achieved target drug concentrations – demonstrated statistically significant improvement on CDR-SB, the trial's primary outcome measure, and ADCS-CGIC, a key secondary outcome measure, in each case, compared to Batch A. In July 2025, we reported additional data from the Extension Phase showing significant, durable treatment effects out to 32 weeks, including a significant risk reduction in clinically significant worsening (≥ 1.5-point increase in CDR-SB) with Batch B neflamapimod treatment compared to control.

The final results of the RewinD-LB Trial were presented in December 2025 at the Clinical Trials in Alzheimer's Disease (CTAD) conference. The key results included:

- Through the first 16 weeks of the Extension Phase, the change in CDR-SB was significantly lower in the Batch B group compared to the Batch A group (difference = -0.57, 95% CI: -0.98, -0.16; p=0.007).

- On ADCS-CGIC, which was administered at Week 8 of the Extension Phase, administration of Batch B led to an improved score (4.02 vs. 4.42 Batch A, $p<0.05$). In addition, in a within-participant analysis, mean ADCS-CGIC score was reduced in participants administered Batch B compared to placebo (4.00 vs. 4.44, $p<0.05$).

- Over the full course of the study, the risk of clinical progression (defined as ≥ 1.5 point increase in CDR-SB score) was reduced by over 50% with Batch B treatment, both vs. Batch A (hazard ratio=0.46 95%CI 0.30-0.69) and vs. placebo (hazard ratio=0.49, 95%CI 0.30-0.80) over 32 weeks of treatment.

- Participants treated with Batch B for all 32 weeks of the Extension Phase demonstrated a statistically significant reduction from baseline in plasma GFAP levels, a validated biomarker of neurodegenerative disease activity, with a median change of -16.0 pg/mL (Interquartile range -35, 6.7) in all participants (N=107; $p<0.001$ for change from baseline; p=0.014 vs. Batch A).

- Additional data from the Extension Phase presented at the 19th International Conference on Alzheimer's and Parkinson's Disease and Related Neurologic Disorders in April 2025 included that Batch B demonstrated improvements on endpoints measuring cognitive fluctuations and working memory.

- Both Batch B and Batch A demonstrated comparable tolerability profiles and no new safety signals were identified during the Extension Phase.

Alignment with FDA on Planned Phase 3 Trial

In November 2025, we announced alignment with the FDA on key aspects of our planned Phase 3 clinical trial of neflamapimod for the treatment of DLB. Based on FDA feedback, we plan to initiate a single, global, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of neflamapimod in approximately 300 participants with DLB by consensus clinical criteria in the second half of 2026, subject to available funding. The trial will exclude patients who have historical evidence of AD co-pathology by brain imaging scan or cerebrospinal fluid sampling. In addition, the trial will be further enriched for participants who do not have AD co-pathology by excluding patients with plasma ptau181 ≥ 21.0 pg/mL at screening. Participants will be randomized 1:1 to receive either oral neflamapimod or placebo for 32 weeks, followed by a neflamapimod only extension for 48 weeks. Worsening of global cognition and function as measured by change CDR-SB – the same primary endpoint as in our RewinD-LB Trial – will be the primary endpoint for the planned Phase 3 trial. Secondary endpoints will include the percentage of participants who have a greater than 1.5-point increase in CDR-SB and other well-established measures of cognitive and motor function. The trial will also include assessments of key biomarkers of the neurodegenerative process, such as GFAP, to further support regulatory review and clinical interpretation. CervoMed expects feedback from other global regulators in the coming months and to announce additional details regarding the planned Phase 3 trial design in early 2026 following these interactions.

As we did between Phase 2a and Phase 2b, we will incorporate several important things we learned from the RewinD-LB Trial into the design of our planned Phase 3 trial, which we believe will further increase the trial's probability of success.

Pre-Phase 3 Manufacturing Improvements

Despite the disparity in performance, Batch A and Batch B were manufactured using the same manufacturing process. While there was no evidence of chemical degradation in our customary release or stability testing prior to the trial's initiation, we conducted additional evaluations of Batch A and Batch B in late 2024 and early 2025 to determine the reason for Batch A's failure to achieve target plasma drug concentrations. Our investigations identified a previously undiscovered mixture of polymorphic forms of neflamapimod's DS. These polymorphic forms have different physical chemistry properties, including solubility, potentially with a time-dependent change in relative amounts of the individual forms. The Batch A capsules were more than three years out from their manufacture date at the time of administration during the RewinD-LB Trial – much older than Batch B and the drug product utilized in our past clinical trials at their respective time of use. We believe this time-dependent change accounted for the reduced performance of Batch A in the RewinD-LB trial, as well as the difference in performance between the two batches despite using the same DS and DP manufacturing processes.

To mitigate the potential for this reduction in performance over time, we identified the most stable polymorphic form, as well as a controlled manufacturing process to reliably manufacture DS that contains only (or predominantly) this stable form. In March 2025, we announced bioavailability data from a Phase 1 trial evaluating this stable crystal form of neflamapimod manufactured using the new, controlled manufacturing process. Following our evaluation of the results, we selected 50mg TID of the stable crystal form of neflamapimod as the dose and dosing regimen for our planned Phase 3 study in patients with DLB. While the PK profiles of 40mg of Batch B and 40mg of the stable crystal form of neflamapimod are largely overlapping, the dose will be increased to 50mg with the intent of ensuring the dosing regimen achieves the plasma drug concentrations observed with Batch B.

Enhanced Patient Enrichment Strategy

At the time RewinD-LB Trial was initiated in mid-2023, 27.2 pg/ml was estimated to be the optimal ptau181 cutoff for excluding patients with AD co-pathology from the trial, based on the limited data set available at that time. However, pre-specified analyses of the Extension Phase data, conducted in March 2025 and presented at the Alzheimer's Association International Conference in July 2025, indicated that lower cutoff points (e.g., 25.2 pg/mL, 23.0 pg/mL, 21.0 pg/mL) led to progressively greater treatment effect size for CDR-SB and ADSC-CGIC in the RewinD-LB Trial, with the greatest effect size at 21.0 pg/mL. This finding was confirmed in a large (N=1298), third-party validation study published in June 2025, indicating that a ptau181 cutoff of 21.0 pg/mL was the high sensitivity cutoff for identifying AD pathology in AD and non-AD dementia (including DLB) by CSF criteria. This means the RewinD-LB Trial was only partially enriched for patients without AD co-pathology, as patients with screening ptau181 between 21.0 pg/mL and 27.2 pg/mL were enrolled in the trial. Based on recent scientific literature, we estimate that between 60-65% of those enrolled in the RewinD-LB Trial using the 27.2 pg/mL cutoff were patients without AD co-pathology, while reducing that cutoff to 21 pg/mL would increase that enrichment rate to approximately 80-90% of the patients.

Accordingly, our planned Phase 3 clinical trial in DLB will be further enriched for patients who do not have AD co-pathology by excluding patients with plasma ptau181 greater than 21.0 pg/mL at screening. In our pre-specified analysis of this cohort in the RewinD-LB Trial, effectively representing our target patient population in Phase 3, we observed even more pronounced clinical effects, including:

- In secondary analyses of data from the RewinD-LB Trial, for both change in CDR-SB and ADCS-CGIC, the magnitude of the effect was greater in the subset of patients without AD co-pathology defined by the lower 21.0 pg/mL screening ptau181 cutoff. Specifically, in a within-participant comparison to placebo among participants who received placebo during Randomized Phase and Batch B during the Extension Phase, Batch B treatment improved change in CDR-SB by 1.12 points (p=0.004 vs. placebo) and the ADCS-CGIC score by 0.82 points (p=0.004 vs. placebo).

- A 75% reduction in the risk of clinically meaningful progression (≥ 1.5-point increase in CDR-SB) over up to 32 weeks of treatment with Batch B treatment compared to placebo.

Other Ongoing DLB Trials

In August 2024, we initiated a Phase 2a trial in Strasbourg, France, to evaluate a twice daily regimen (80mg BID) of neflamapimod in 26 patients with DLB with MCI (MoCA score ≥ 18 during screening). Unlike our RewinD-LB Trial, the patient population in the Strasbourg trial was not enriched for patients without AD co-pathology. Rather, the primary objective of the trial is to obtain additional safety and PK data on a dosing regimen not previously evaluated in any of our clinical trials (80mg BID) that, among other things, may provide additional dosing flexibility in future trials. On an exploratory basis, we will also collect data on basal forebrain atrophy, as measured by MRI, and a broad range of clinical endpoints.

In the first quarter of 2025, all patients completed dosing in the trial and, based on the topline data, the primary objectives around safety and PK were achieved. Neflamapimod was well tolerated with no new safety signals being identified. The mean $C_{trough,}$ defined as 12-hour post last dose plasma drug concentrations, demonstrated a dose-proportionate increase. One participant discontinued early due to Grade 3 elevations in ALT and AST, but there was no observed increase in bilirubin levels, values normalized after treatment discontinuation, and concomitant medications known to affect liver enzymes were considered to have been a contributory factor. We plan to present clinical endpoint and brain MRI results from the trial at a future medical conference.

Neflamapimod's Potential in Additional Indications

Frontotemporal Disorders // Primary Progressive Aphasia

FTDs are a category of neurodegenerative disorders characterized by progressive deterioration in behavior, personality, and language abilities, typically affecting individuals between the ages of 40 and 65 including an estimated tens of thousands of individuals in the US 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 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, though the latter is not considered an FTD subtype. 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 effects of p38α on axonal transport and tau pathologies, as well as atrophy of the BFC system being a driver of disease and the mechanisms that neflamapimod targets being operative in FTD. Additionally, when assessed by MRI, the volume of the basal forebrain is reduced, relative to age-matched healthy control, most prominently 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 transgenic harboring P301L mutation). Based in part on these nonclinical results, in November 2024, the FDA granted neflamapimod Orphan Drug Designation for the treatment of frontotemporal dementia.

To best align with the scientific rationale described above, we have chosen to evaluate neflamapimod in nfvPPA because more than 90% of patients with this subtype of FTD at autopsy have tau pathology, rather than TDP-43 pathology. In 2025, we initiated our Phase 2a trial evaluating neflamapimod in up to 25 participants with nfvPPA. Participants in the trial will receive six months of open label treatment with neflamapimod, followed by a three month blinded (randomized 1:1 placebo or continued neflamapimod) washout period. The primary objective is to evaluate the safety and tolerability of neflamapimod in this patient population. In addition, treatment effects on a range of clinical measures of aphasia and plasma neurodegeneration biomarkers, including GFAP and NfL, will be evaluated. We expect to report initial plasma biomarker from the trial in mid-2026, subject to available funding.

Acute Indication: Recovery after Ischemic Stroke

A treatment to improve recovery from stroke remains a significant unmet medical need. Every year, more than 795,000 people in the US 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. 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, the window for therapeutics that could improve recovery is days and even weeks after an acute stroke. From a drug development perspective, 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. 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.

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. The scientific rationale for evaluating neflamapimod to promote recovery after stroke is that the BFC 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 nonclinical 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 nonclinical 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).

Based upon these data and hypotheses, we initiated our ongoing RESTORE Trial, a Phase 2 placebo-controlled trial evaluating neflamapimod in up to 90 participants recovering from a moderate to moderately-severe anterior circulation ischemic stroke, in the second quarter of 2025. Patients will be enrolled between 3 and 7 days after the onset of their qualifying stroke event, and randomized 1:1 to placebo or neflamapimod for 12 weeks. The primary objective of the study is to evaluate effects of neflamapimod on recovery of motor function. The major outcome measures include change from baseline to week 12 in the Fugl-Meyer Assessment of Motor Recovery after Stroke (FMMS), Timed Up and Go (TUG) test and the National Institutes of Health Stroke Scale (NIHSS) motor score. We anticipate completing enrollment at the end of the second quarter of 2026 and expect to report topline data in the second half of 2026, subject to available funding.

Amyotrophic Lateral Sclerosis (ALS)

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord that control voluntary muscle movement and breathing. Over the course of the disease, people lose the ability to move, sometimes also to speak, and eventually, to breathe. There are no approved therapies that stop or reverse the progression of ALS. Approximately 168,000 people worldwide live with ALS, with an estimated 90-95% of cases occurring without a family history of the condition.

In ALS, p38α is aberrantly activated and plays a key role in impairing axonal transport—a fundamental physiologic defect in the disease. Restoring axonal transport through p38α inhibition has been demonstrated both in vitro and in vivo, including in the SOD1 transgenic mouse model. More recently, independent nonclinical studies have further validated p38α as a disease-relevant, convergent target in ALS and, we believe, demonstrated the potential of neflamapimod. For example, recent third-party research related to both TDP-43 pathology and C9ORF72-associated ribotoxic stress response have independently concluded that p38α inhibitors may find important applications in ALS.

In February 2026, we announced that neflamapimod has been selected for inclusion in EXPERTS-ALS, a platform that facilitates rapid testing of potential ALS to identify promising drug candidates and potentially accelerate their path to regulatory approval. Funded by the United Kingdom National Institute for Health and Care Research and leading motor neuron disease charities and sponsored by Sheffield Teaching Hospitals NHS Foundation Trust, EXPERTS-ALS assesses potential therapies through a randomized, multicenter, open-label, multi-arm trial that evaluates investigational medicines through the measurement of the blood biomarker NfL. NfL levels are significantly elevated in ALS patients due to accelerated neuroaxonal damage and correlate with the rate of disability progression and survival. Neflamapimod will be initially evaluated in approximately 35 participants with ALS for 18-24 weeks to determine its impact on NfL levels, with the potential for further evaluation in up to a total of 80 patients. Secondary and exploratory endpoints include several clinical and survival measures. We anticipate the first patient will be dosed with neflamapimod in EXPERTS-ALS trial in the fourth quarter of 2026, subject to available funding.

Additional Neflamapimod Development Background

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 chronic 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 CNS disease 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 CNS 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 the doses utilized in our ongoing and anticipated clinical trials. The CNS findings indicated potential 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 plasma drug concentrations associated with doses we are using in our clinical trials in the US are at least ten-fold lower than the no adverse effect level for these effects.

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. In addition, the FDA granted neflamapimod Fast Track Designation for the treatment of DLB in October 2019 and Orphan Drug Designation for the treatment of frontotemporal dementia in November 2024.

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 to the no adverse effect level in long-term animal toxicity studies . At the present time, based on agreements with the FDA and on our current understanding of plasma drug levels achieved with neflamapimod in humans, this partial clinical hold effectively limits our clinical dosing in the US in patients with a weight of greater than or equal to 50kg (110 pounds) to the plasma drug concentrations associated with doses we are using in our ongoing and anticipated clinical trials.

In Europe, clinical trial applications in support of our clinical trials have been reviewed and approved 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. Our ongoing Phase 2a trial in Strasbourg, France, which is not subject to the FDA's partial clinical hold, is evaluating an 80mg BID dosing regimen in participants with mild-to-moderate DLB.

Clinical Safety Results

Neflamapimod's 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 550 participants to date, including over 350 participants in Phase 2 clinical trials in CNS disorders. We also have several ongoing and planned clinical trials to further evaluate the safety, tolerability and PK profile of neflamapimod, including doses higher than the 40mg TID dose evaluated in our recent RewinD-LB Trial.

In the RewinD-LB Trial, adverse events were similar to the safety profile seen in all other trials and are shown in the table below:

Overview of Treatment-emergent Adverse Events (TEAEs) (≥5%) During the Randomized Phase (Safety Set) in Phase 2b RewinD-LB Study EIP21-NFD-504

System Organ Class Preferred Term	**Neflamapimod (40 mg TID) (N=79) n (%)**	**Placebo (N=80) n (%)**
Any TEAE	58 (73.4)	59 (73.8)
Fall	12 (15.2)	15 (18.8)
COVID-19	8 (10.1)	3 (3.8)
Diarrhea	6 (7.6)	3 (3.8)
Urinary tract infection	5 (6.3)	6 (7.5)
URTI	5 (6.3)	4 (5.0)
Headache	5 (6.3)	10 (12.5)
Fatigue	5 (6.3)	6 (7.5)
Dizziness	4 (5.1)	3 (3.8)
Confusional state	4 (5.1)	1 (1.3)
Alanine aminotransferase increased	4 (5.1)	1 (1.3)
Back pain	4 (5.1)	1 (1.3)
Hallucination	2 (2.5)	5 (6.3)

In the Extension Phase of the RewinD-LB Trial, the profile remained similar with the following events reported by more than 5% of participants: fall, UTI, COVID-19, hallucination and diarrhea. In our previously completed clinical trials, the most commonly reported non-serious TEAEs included were headache, respiratory infection, diarrhea, fall, and somnolence all mild to moderate in severity. Headache, diarrhea, and somnolence appear to have the strongest association with neflamapimod treatment.

As of November 11, 2025, in clinical trials evaluating neflamapimod in patients with AD and DLB, there have been 44 SAEs reported in 273 participants treated with neflamapimod. The events of cerebral hemorrhage, syncope, pneumothorax, subcutaneous emphysema, and rib fracture were considered possibly related to neflamapimod by the trials' investigator(s).

P38 MAPK inhibitors as a class have been associated liver enzyme elevations including transient, asymptomatic liver enzyme (transaminase) elevations without signs otherwise of hepatotoxicity (e.g., no elevation in bilirubin). ALT and AST and other liver function tests are routinely monitored in participants in neflamapimod clinical studies. Across the neflamapimod clinical development program, liver function testing elevations have been observed, primarily involving asymptomatic increases in ALT and AST. Most events were mild to moderate in severity, transient, and reversible upon dose interruption or discontinuation. No cases consistent with Hy's Law were identified. Overall, the hepatic safety profile of neflamapimod supports continued clinical development with appropriate monitoring.

Among approximately 350 participants exposed to neflamapimod across the most recent clinical trials in AD, HD, DLB, recovery after stroke, and PPA, ALT or AST elevations >3× ULN were reported in 2 % of subjects. Elevations >5× ULN occurred in 0.2%, and elevations >10× ULN were uncommon (<1%). Increases in total bilirubin were infrequent and generally not temporally associated with transaminase elevations. In the RewinD-LB Trial, one of 80 (1.3%) participants treated with neflamapimod discontinued because of liver enzyme elevation during the Randomized Phase but the event was determined to be reversible and not associated with bilirubin elevation. During the trial's Extension Phase, none of the 149 neflamapimod recipients discontinued for liver enzyme elevation.

Nonclinical Studies

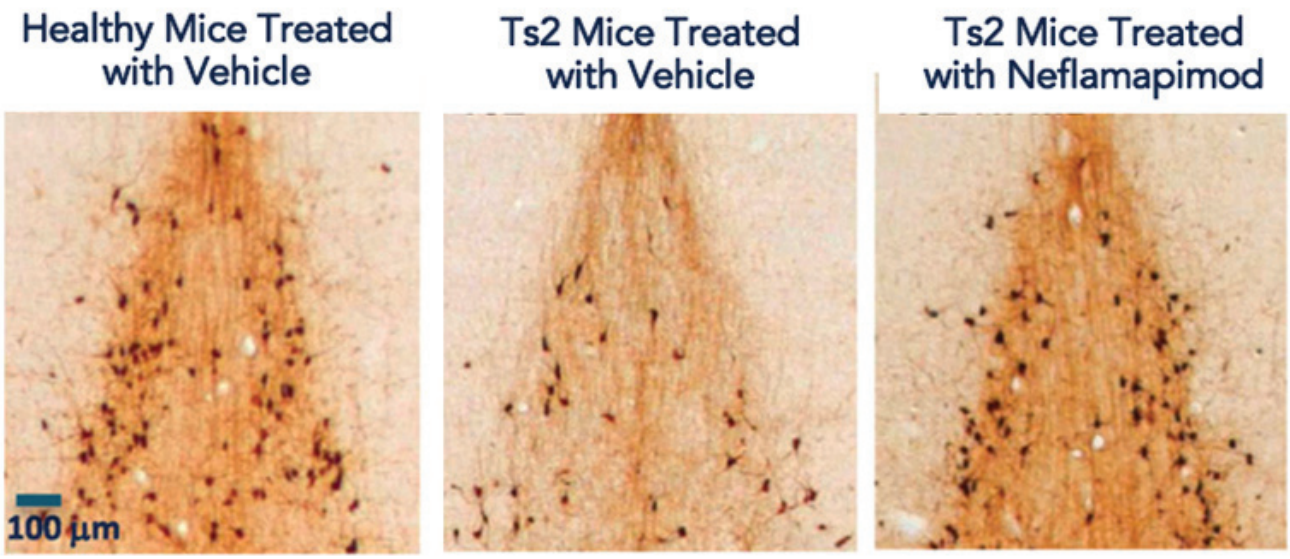
Ts2 Transgenic Mice

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 EOAD 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 BFC system. Accordingly, Ts2 mice provide an ideal opportunity to evaluate the effects of drug treatment on BFC dysfunction and degeneration.

In a nonclinical study, wild-type mice, referred to as either wild-type or 2N, and Ts2 mice were treated over 28 days with either control or neflamapimod. 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 control-treated TS2 mice compared to control-treated wild-type 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, such that the number of ChAT+ neurons were similar to those seen in wild-type mice ($p<0.001$). Neflamapimod treatment also normalized Rab5 activity and phosphorylated (i.e., activated) p38 MAP kinase and its downstream substrates.

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



Cholinergic neurons, as assessed by staining positive for ChAT+ neurons 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 BFC system is not due to cell death. Rather, the "degeneration" and loss of such BFC neurons appears to be due to a loss of cholinergic phenotype and functional properties, and neuronal shrinkage. In animal studies, all of this disease progression can be reversed, evidenced by the increased number of cholinergic neurons. This is not a regenerative effect, however. Rather, we believe it reflects that treatment with neflamapimod is restoring the function of diseased neurons, 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 patients with AD discussed above in whom an increase in the volume of BFC neurons was observed in the NbM.

Aged Rat Model

To obtain nonclinical 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 BFC dysfunction and degeneration.

The results of these nonclinical studies 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 control–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., cognitive deficits were fully reversed).

Vertex Agreement

In August 2012, 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. This decision was made, in part, based on our team's previous direct experience with this compound, our understanding of its profile, and emerging science around p38α in the brain. In August 2014, we exercised that option to acquire the license to neflamapimod.

The Vertex Agreement sets forth certain milestone events and the related payments 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 the filing of an NDA with the FDA for marketing approval of neflamapimod in the US and/or a similar filing for a non-US major market. The Vertex Agreement also provides that we will make royalty payments to Vertex in the event aggregate net sales 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 one-time 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 $117.0 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, completion of multiple Phase 2 clinical trials of neflamapimod, and our ongoing development efforts.

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 in the US, expiring in 2038, 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.

However, we believe these novel co-crystals of neflamapimod may provide additional optionality to multiple aspects of our development strategy, including related the partnering and/or commercialization of neflamapimod across the multiple indications in which it has demonstrated potential.

Sales and Marketing

We do not currently have any infrastructure for the sales, marketing, or distribution of an approved DP. 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 global or regional 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 DS is manufactured at established commercial CMOs that are approved for and manufactures DS both for investigational use and marketed products. We have used the same manufacturer for our neflamapimod DS in all our clinical trials prior to 2026 but have recently begun working with a second DS CMO to, in part, diversify our prior sole supplier risk. We anticipate utilizing these or similar CMOs for the manufacture of DS to be used in future clinical trials, as well as potentially for commercial use if neflamapimod is approved. However, supplies of our neflamapimod DS 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.

We also currently rely on a third-party CMO (different than those for DS) for the manufacture of our neflamapimod DP. We have used the same manufacturer for our neflamapimod DP in all our clinical trials to date but have recently begun working with a second DP CMO to, in part, diversify our prior sole supplier risk. If neflamapimod is ultimately approved for commercial sale, we expect to continue to rely on third-party contractors for manufacturing the DP. Although we may 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 DP with our current manufacturing providers, or with any alternate manufacturers.

For a further description of our planned pre-Phase 3 manufacturing improvements and certain risks related to our manufacturing, see "*Alignment with FDA on Planned Phase 3 Trial – Pre-Phase 3 Manufacturing Improvements,*" "*Item 1A. Risk Factors – Risks Related to Our Product Development and Regulatory Approval – Our reliance on third parties for the production of neflamapimod may result in delays in our clinical trials or regulatory approvals and may impair the development and ultimate commercialization of neflamapimod, which would adversely impact our business and financial position,*" and "*Item 1A. Risk Factors – Risks Related to Our Product Development and Regulatory Approval – Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.*"

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 in later-stage development 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 Cognition Therapeutics, Inc., although their lead indication remains AD and, in March 2026, they announced plans to advance zervimesine as a symptomatic treatment for DLB-related psychosis, rather than as a treatment for the underlying disease process. In addition, we are also aware of a recent NIA-supported, Phase 2 clinical trial of nilotinib, an FDA-approved leukemia drug, is evaluating its potential to break down abnormal alpha-synuclein proteins in DLB. However, we are not aware of any other companies developing a treatment specifically targeting DLB patients without AD co-pathology, the target patient population of our planned Phase 3 trial, or utilizing our mechanism of action.

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, nonclinical 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 US and in jurisdictions outside of the US 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 US, 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 US, Europe, and Japan. In China, we hold an issued patent related to improving cognition in certain conditions including improving functional recovery after stroke, as well as a pending application with respect to certain other claims. 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 US 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 US, 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 in the US for the treatment of patients with MCI to improve episodic memory and a pending application in Europe, with respect to which we received in notice of allowance in late 2025. The issued patent in the US is set to expire in 2037, and other patents that issue in this family in the future, if any, are also expected to expire in 2037.

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

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

- The eighth patent family relates to treatment of gait dysfunction related to neurodegenerative disease. In this family we have pending applications in the US, Europe, Japan, China, Canada, Australia, Hong Kong, and Israel. Patents that issue in this family, if any, are expected to expire in 2041.

- The ninth patent family relates to treatment of a subpopulation of patients having DLB but no substantial Alzheimer's like tau pathology (i.e., no AD co-pathology). In this family we have pending applications in the US, Europe, Japan, China, Canada, Australia, New Zealand, Korea, and Israel. Patents that issue in this family, if any, are expected to expire in 2042.

- The tenth patent family relates to treatment of aphasia. In this family we have pending applications in the US and other jurisdictions. Patents that issue in this family, if any, are expected to expire in 2044.

Pursuant to the terms and conditions of the Vertex Agreement, Vertex has granted us an exclusive license under specified Vertex patent rights, including US 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 US 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 "Item 1A. Risk Factors—Risks Related to Our 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.

US Government Regulation of Drug Products

In the US, the FDA regulates drugs under the FDCA and its implementing regulations. Failure to comply with the applicable US 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 US 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 DP 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 US.

Nonclinical Studies and IND

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. In December 2022, Congress 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 trial 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. Both the NIH and the FDA have 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. Historically, two adequate, well-controlled multicenter trials have been required by the FDA for drug product approval. However, in early 2026, the FDA announced it has changed the base standard to require a single adequate, well-controlled clinical trial plus certain confirmatory evidence to support approval, although the FDA has not yet clarified what types or amount of confirmatory data will be required.

- *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.

Reports detailing the progress of and safety data from 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 amended the FDCA in December 2022 to require each sponsor of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support MA, 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. 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 physiochemical 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 DP. 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. For a further description of our planned pre-Phase 3 manufacturing improvements to address the stability issues identified during our RewinD-LB Trial, see "*Alignment with FDA on Planned Phase 3 Trial – Pre-Phase 3 Manufacturing Improvements*" and "*Item 1A. Risk Factors – Risks Related to Our Product Development and Regulatory Approval.*"

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, nonclinical 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 nonclinical 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 DP 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 US.

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 products with Orphan Drug designation or 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," within 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 trial 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 the 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. In September 2025, the FDA began publishing CRLs, with trade secret and confidential commercial information redacted, soon after issuing them to the respective sponsors, breaking with long-standing agency tradition of publishing CRLs with approval documentation after the product is approved. If and when the deficiencies cited in the CRL 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, Breakthrough Therapy, Priority Review Designations, and CNPV

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 a Breakthrough Therapy is also eligible for Accelerated Approval if the relevant criteria are met.

In 2025, the FDA created a new pilot program called the CNPV with the goal of radically expediting the drug and biological product review and approval process. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

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. None of these programs 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. Congress amended the FDCA in December 2022 to provide the FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs or biologics previously being considered for accelerated approval. Under the act's amendments to the FDCA, the 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 the FDA's website. The amendments also give the 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.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the US, or a patient population greater than 200,000 individuals in the US and when there is no reasonable expectation that the cost of developing and making available the drug in the US will be recovered from sales in the US for that drug. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the therapeutic agent and its potential orphan indication are disclosed publicly by the FDA.

If a drug product that has Orphan Drug Designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan product exclusivity or if the FDA finds that the holder of the orphan product exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Orphan product exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application user fee.

A drug with Orphan Drug Designation may not receive orphan product exclusivity if it is approved for a use that is broader than the indication for which it received Orphan Drug Designation. In addition, orphan product exclusive marketing rights in the US may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

We have obtained Orphan Drug Designation in the US for neflamapimod in frontotemporal dementia.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our US 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 US 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.

Hatch-Waxman Exclusivity

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.

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 US 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 DP 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 CMOs 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 MAs, 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 US The DSCSA mandates resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers. The DSCSA also replaced certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme, requiring uniform national standards for wholesale distribution and, for the first time, for third-party logistics providers. 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 US Health Care Laws and Regulations

If our product candidates are approved in the US, we will have to comply with various US 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 personal data, including health information in some circumstances, and many such laws 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 US, 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 US 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 US 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. In addition, future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA's regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, negotiations on the next FDA user fee reauthorization package began in mid-2025 and the resulting agreement is expected to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program must be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry. 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 US 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. The US Congress has considered reductions in Medicare reimbursement levels for medicines 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 DPs. Notably, the CREATES Act was enacted to address 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 of an RLD to conduct certain comparative testing required by the FDA, some attributed the inability to timely obtain such 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." Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

In August 2022, the IRA was signed into law. Among other things, the IRA has multiple provisions that may impact the prices of DPs that are both sold into the Medicare program and throughout the US For example, 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 DP's price increases faster than the rate of inflation. This calculation is made on a DP by DP basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a DP that is paid for by Medicare Parts B or D. Additionally, 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 DP 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 announcing the first round of negotiated "maximum fair" prices for the first ten drug products in August 2024, which will become applicable for payment year 2026. The second round of negotiated priced for 15 drug products was announced in November 2025, and CMS published the next group of drug products selected for negotiation in January 2026. However, the IRA's impact on the pharmaceutical industry in the US remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the US 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.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of December 2025, the Trump Administration secured deals with five major drug manufacturers to offer certain drugs at most-favored-nation prices. In addition, recent US federal actions include initiatives incorporating most-favored-nation (international reference pricing) concepts for certain prescription drugs, as well as agency testing of new payment models that could tie Medicare reimbursement or manufacturer rebates to prices in specified reference countries.

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. For example, in recent years, several states have formed PDABs. Much like the IRA's drug price negotiation program, these PDABs have attempted to implement UPLs on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. We expect that federal, state and local governments in the US will continue to consider legislation directed at lowering the total cost of healthcare. Furthermore, in December 2020, the US 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 launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that appear to be contributing to additional federal and state legislative and regulatory proposals, as well as enforcement action and private litigation, targeting PBM operations, pharmacy networks, and financial arrangements. In February 2026, President Trump signed into law several PBM regulatory reforms as part of a federal budget package, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only bona fide service fees from drug companies when providing services under Medicare Part D. The Department of Labor also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under ERISA. If finalized as proposed, the Department of Labor rule would also allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. Additional proposals and legislative changes aimed at PBMs and their business practices are likely to continue to be introduced and considered in Congress and by executive agencies. Significant efforts to change the PBM industry as it currently exists in the US 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 US 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 US, 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, which was subsequently finalized and adopted in December 2025. The 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 MA. 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 MA 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 MA 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.

Other Regulatory Requirements

We are or may become subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement authority, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have an adverse effect on our ability to operate our business and generate revenues. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could negatively impact our business, operating results and financial condition.

Our People

Overview

As of December 31, 2025, we had 15 employees, all of whom we classify as full-time employees. We had the same number of employees as of December 31, 2024. 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.

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

Company Culture

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, particularly as it relates to attracting and retaining talent with relevant experience in the biotechnology and pharmaceutical sectors. Therefore, we strive to provide our employees a total rewards package that is competitive with our peer companies. 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 opportunity to benefit financially from our potential future growth through stock option grants. As these grants generally vest over a three- or four-year period, we believe these grants also help promote retention and align the interests our employees and stockholders.

Employee Engagement, Safety and Wellness

At CervoMed, 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 and professional, promotes teamwork and trust, and affords all of our employees the opportunity to contribute to the best of their abilities. We have also made investments designed, in part, to support our employees' work-life balance, including, in recent years, investing in technology solutions to support increased work-from-home capabilities and moving to an unlimited paid leave policy.

Development and Training

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 experiences. 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. In addition, many of our employees attend scientific, clinical, technological, and other meetings and conferences relevant to their area of expertise.

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 brain 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, Director, President and Chief Executive Officer, John Alam, MD*, has 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. Dr. Alam is an emerging drug development leader in neurodegenerative diseases, including having been the global head of all research and development 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.,* has more than 30 years' experience and previously held executive leadership posts in several multinational life sciences firms. Dr. Grégoire also has extensive experience with corporate governance and board operations. She is currently chair of the board of directors of Abivax S/A (ABVX), a publicly-traded life sciences company, and on the board of directors of F2G, a private biotechnology company. Previously, Dr. Grégoire was chair of Corvidia Therapeutics (acquired by Novo Nordisk) and a member of the board of directors of Novo Nordisk A/S (NYSE: NVO), Revvity (Nasdaq: RVTY) (formerly known as PerkinElmer, Inc. (NYSE: PKI)), ViFor Pharma (acquired by CSL) and Cubist Pharmaceuticals (acquired by Merck).

- *The Chair of our Board, Joshua S. Boger, PhD*, 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 an Investor Director of mOm Incubators, Ltd., a private, UK-based, medical device company. 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 Directors

The table below sets forth, as of March 11, 2026, certain information concerning our current directors.

Name	Age	Director Since
Joshua S. Boger, Ph.D. (Chair)	74	2024
John Alam, M.D.	64	2023
Sylvie Grégoire, PharmD.	64	2023
Jane Hollingsworth, J.D.	67	2020
Jeff Poulton	58	2023
David Quigley	58	2025
Marwan Sabbagh, M.D.	60	2023
Frank Zavrl	60	2023

Our Executive Officers

The table below sets forth, as of March 11, 2026, certain information concerning our current executive officers.

Name	Age	Position
John Alam, M.D.	64	President and Chief Executive Officer (Principal Executive Officer)
Kelly Blackburn, M.H.A.	62	Executive Vice President, Clinical Development
Mark De Rosch, Ph.D., FRAPS	62	Executive Vice President, Regulatory and Govt. Affairs and Program Mgmt.
William Elder	43	Chief Financial Officer and General Counsel (Principal Financial Officer)
Marco Verwijs, Ph.D.	49	Executive Vice President, Technical Operations
Matthew Winton, Ph.D.	48	Chief Commercial and Business Officer

Our Scientific Advisory Board

We have assembled a highly qualified SAB comprised of thought leaders in the fields of cell biology, intracellular signal transduction, neurotherapeutics, and translational neuroscience.

Name	Affiliated Entity
Ole Isacson, Dr.Med.Sci.	Professor of Neurology at Harvard Medical School, Founding Director of the Neuroregeneration Research Institute at McLean Hospital
Lewis Cantley, Ph.D.	Professor of Cell Biology at Harvard Medical School. Prior to this appointment, he was the Margaret and Herman Sokol Professor and Meyer Director of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medical College/Ronald P. Stanton Clinical Cancer Program at New York Presbyterian Hospital (2012-22)
Heidi McBride, Ph.D.	Canada Research Chair in Mitochondrial Cell Biology, Professor in the Department of Neurology and Neurosurgery at McGill University

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, which was treated as a "reverse recapitalization" under US 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 Annual Report 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.

ITEM 1A. RISK FACTORS

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

You should carefully consider the risk factors set forth below as may be updated by our subsequent filings under the Exchange Act together with all the other information in this Annual Report, including our consolidated financial statements and the related notes included in Part II, Item 8 – Financial Statements and Supplementary Data of this Annual Report and the information set forth in Part II, Item 7A -- 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 we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could, nevertheless, adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.

Summary of Risk Factors

- We are a clinical stage biopharmaceutical company and have incurred significant losses since our inception. We expect our net losses to continue for the foreseeable future. We are not currently profitable and may never achieve or sustain profitability. We are unable to predict the extent of future losses or when it might become profitable, if ever. This raises substantial doubt regarding our ability to continue as a going concern.

- We will require additional capital to fund our operations, including any Phase 3 trial evaluating neflamapimod in patients with DLB. If we fail to obtain necessary financing on acceptable terms, or at all, we may not be able to complete the development and commercialization of neflamapimod.

- We currently do not have, and may never have, any products that generate significant revenues.

- We are heavily dependent on the success of our lead product candidate, neflamapimod, which is still under clinical development. If neflamapimod does not receive regulatory approval or is not successfully commercialized, our 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 our planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that we may pursue, will be successful. If we are ultimately unable to obtain regulatory approval for neflamapimod on a timely basis, or at all, our business will be substantially harmed.

- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We 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 we may develop or acquire.

- We have concentrated our 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 brain disorders is extremely difficult and is subject to a number of unique challenges. In addition, our 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 our control.

- Results of nonclinical studies, early clinical trials, and analyses of open-label results, including the Extension Phase results from the RewinD-LB Trial, may not be indicative of results obtained in later large, well-controlled, randomized clinical trials. In addition, preliminary, topline and interim data from our clinical trials that we 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.

- We face substantial competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

- If we do not adequately protect our proprietary rights, we may not be able to compete effectively.

- We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for their future viability.

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

- Our future success depends in large part on our ability to retain our key employees, as well as our ability to attract, train and motivate additional qualified personnel. We may also encounter difficulties in managing our growth, which could disrupt our operations.

- AI presents risks and challenges that can impact our business including by posing security risks to confidential information, proprietary information, and personal data, as well as emerging, unknown business risks.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital

We are a clinical stage biopharmaceutical company and have incurred significant losses since our inception. We expect our net losses to continue for the foreseeable future. We are not currently profitable and may never achieve or sustain profitability. We are unable to predict the extent of future losses or when we might become profitable, if ever. This raises substantial doubt regarding our ability to continue as a going concern.

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. We have incurred net losses in each fiscal year since our inception, and as of December 31, 2025, we had an accumulated deficit of approximately $97.7 million. We expect to incur net losses for the foreseeable future as we incur significant clinical development costs related to the advancement of neflamapimod. We have not commercialized any products and have never generated revenue from neflamapimod or any other product. In order to obtain revenues from any product candidate, we must succeed, either alone or in collaboration with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

We expect to incur significant additional operating losses for at least the next several years as we advance neflamapimod through clinical development, conduct clinical trials, seek regulatory approval, and commercialize neflamapimod, if it is ultimately approved for marketing. The costs of advancing product candidates into each 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, we are unable to accurately predict the timing or amount of increased expenses, or when or if we will be able to begin generating revenue from the commercialization of neflamapimod, let alone achieve or maintain profitability.

The amount of our future net losses will depend, in part, on the rate of future growth of our expenses, if and when neflamapimod is approved for marketing in various jurisdictions and our ability to generate revenues from any drug candidate that may ultimately be approved. If we are 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, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain it, which could materially and adversely affect our business.

As discussed further in Note 2 to our consolidated financial statements included elsewhere in this Annual Report, we have a history of operating losses and expect to continue to incur losses in the foreseeable future, which raises substantial doubt regarding our ability to continue as a going concern within one year after the date our consolidated financial statements are issued. As described in further detail elsewhere in this Annual Report, our ability to continue as a going concern is dependent on our ability to raise capital and pursue our business strategies to fund operations and future business plans. 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 intend to continue to seek funds through equity offerings, debt financings, royalty arrangements, or other dilutive or non-dilutive capital sources, including potential collaborations, licenses and/or 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 such securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through 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 sufficient capital when needed, we may need to delay, reduce or terminate planned activities to reduce costs, including 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.

Additionally, volatility in the capital markets and general economic and geopolitical conditions in the US and globally may be a significant obstacle to raising the required funds as and when needed. Our consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. If the going concern basis were not appropriate for these consolidated financial statements, adjustments would be necessary in the carrying value of assets and liabilities, the reported expenses, and the balance sheet classifications used. If we are unable to continue as a going concern, our stockholders could suffer the loss of all or a substantial portion of their investment.

We will require additional capital to fund our operations. If we fail to obtain necessary financing on acceptable terms, or at all, we may not be able to complete the development and commercialization of neflamapimod.

We expect 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 our planned clinical trials and costs associated with our license agreement with Vertex, under which we are obligated to make certain payments in connection with the achievement of specified events.

Until such time, if ever, that we can generate sufficient product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings and/or corporate collaboration, licensing arrangements and grants. Based upon our current operating plan, we believe that our cash and cash equivalents as of December 31, 2025, will not be sufficient to enable us to fund our operating expenses and capital expenditure requirements for a period of at least 12 months following the issuance of the consolidated financial statements included elsewhere in this Annual Report without an additional equity or debt financing.

However, our estimates and expectations regarding our cash runway are based on assumptions that may prove to be incorrect, and changing circumstances could cause us to consume capital faster or in different ways than we currently expect. For example, our planned clinical trials may be more expensive, time-consuming, or difficult to implement than we currently anticipate. Because the length of time and activities associated with the successful development of neflamapimod are highly uncertain, we are unable to estimate the actual funds we will require to complete research and development and ultimately commercialize our drug candidate for one or more indications.

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 our ongoing and future clinical trials evaluating neflamapimod in DLB and other indications;
- 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 obligations 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 our grants from organizations, foundations, and governmental entities;

- 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.

We 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 us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. If we are unable to secure additional capital in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue our development or commercialization activities for neflamapimod.

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

We currently do not have, and may never have, any products that generate significant revenues.

We are a clinical-stage biopharmaceutical company focused on developing treatments for age-related brain disorders, currently have no products that are approved for commercial sale, and it is possible we may never be able to develop a marketable product. To date, we have not generated any revenues from our lead product candidate, neflamapimod, or from any other product candidate. We cannot guarantee that neflamapimod, or any other product candidate that we 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 US 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, we 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. We may not achieve any of these objectives.

We cannot be certain that our ongoing trials 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 us will yield a drug candidate suitable for investigation through clinical trials. Even if we are 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.

We may be required to make significant payments to Vertex in connection with our license agreement.

Pursuant to the Vertex Agreement, we 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, we are 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 we would be obligated to make to Vertex, if and when such events occur.

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

We may expend our 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.

We intend to focus our limited financial and other resources on developing neflamapimod and future product candidates for specific indications that we identify as most likely to succeed, in terms of both regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us 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 we do not accurately evaluate the commercial potential or target market for a particular product candidate, we 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 us to retain sole development and commercialization rights to such product candidate.

Our business may be impacted by macroeconomic conditions, including fears concerning the financial services industry, inflation, volatility in interest rates and volatile market conditions, and other uncertainties beyond our control.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Our ability to effectively run our business could be adversely affected by general conditions in the global economy and in the financial services industry. Various macroeconomic factors could adversely affect our business, including fears concerning the banking sector, volatility in inflation and interest rates and overall changes in economic conditions and uncertainties. A severe or prolonged economic downturn could result in a variety of risks, including our ability to raise additional funding on a timely basis or on acceptable terms, or at all. A weak or declining economy could also impact third parties upon whom we depend to run our business. Concerns over bank failures and bailouts and their potential broader effects and potential systemic risk on the banking sector generally and on the biotechnology industry and its participants may adversely affect our access to capital and our business and operations more generally. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general.

Certain regulatory limitations may affect our ability to consummate future financings.

If our public float as measured pursuant to General Instruction I.B.6 to Form S-3 falls below $75 million, we will be subject to the restrictions set forth in General Instruction I.B.6 to Form S-3 that limit our ability to conduct primary offerings under a Form S-3 registration statement to one-third of our public float in any 12 calendar months – often referred to as the "baby shelf rules." As of March 11, 2026, our public float calculated in accordance with General Instruction I.B.6 of Form S-3 was approximately $47.5 million and, accordingly, we will be limited by the "baby shelf rules" unless and until our public float as measured pursuant to General Instruction I.B.6 to Form S-3 exceeds $75 million.

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

In connection with the NIA Grant, we may be subject to routine audits by certain government agencies. As part of an audit, these agencies may review our 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 our expenditures are found to be unallowable or allocated improperly or if we have otherwise violated terms of the NIA Grant, the expenditures may not be reimbursed and/or we may be required to repay funds already disbursed. Any such audit may result in a material adjustment to our results of operations and financial condition and harm our ability to operate in accordance with our business plan.

Risks Related to Our Product Development and Regulatory Approval

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

We have invested almost all of our efforts and financial resources to date in the development of neflamapimod. To date, we have 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 our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our future success is substantially dependent on our 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.

We expect a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of neflamapimod's clinical development. In order to be successful, we 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 we can generate any revenues from commercial sales. We cannot be certain that we will be able to successfully complete any or all of these activities.

Furthermore, we have not submitted an NDA to the FDA or comparable applications to other regulatory authorities for neflamapimod, and we do 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 we can file an NDA or any other application seeking approval of neflamapimod for the treatment of DLB, or any other indication. If we are unable to obtain the necessary regulatory approvals for and commercialize neflamapimod, it would materially adversely affect our financial position, and we may not be able to generate sufficient revenue to continue our 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 our planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that we may pursue, will be successful. If we are ultimately unable to obtain regulatory approval for neflamapimod on a timely basis, or at all, our 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. We may experience difficulties in initiating and completing the clinical trials that we intend to conduct, and we do 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 our clinical trials, we face significant risks, including that our 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 our earlier nonclinical studies and clinical trials, the FDA may disagree with our interpretation of the clinical trial data or how those data inform the design of future clinical trials, and the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to support approval.

We cannot predict with any certainty if or when we might complete our 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 our failure to obtain regulatory approval to market neflamapimod as a treatment for DLB or any other indication, which would significantly harm our 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 we believe the data collected from our 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, we may be required to conduct additional nonclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market neflamapimod or any of other product candidates, if approved.

We are 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 US, 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. We 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 we 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 our 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. Nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and 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.

We may experience numerous unforeseen events during, or as a result of, our clinical trials that could delay or prevent our 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 we anticipate 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 we are 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 GCP 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 our CROs and other third parties, or the cost of clinical trials being greater than we anticipated;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of DP 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 our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies, clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, the IRB or a Data Safety Monitoring Board if one is used for our clinical trials, may require that we suspend or terminate our 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 our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO, and delays or failure by our CMOs or we to make any necessary changes to such manufacturing process;
- the FDA or comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us 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 our clinical trial design and our 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 our clinical trials.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval for our 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 our products or inhibit our ability to successfully commercialize our 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 our commercialization prospects, substantially increase the costs of commercializing neflamapimod, and severely harm our business and financial condition.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through nonclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, if we change the formulation of neflamapimod, this could increase our costs and/or could delay regulatory approval.

Any of these changes could cause our product candidate to perform differently and affect the results of clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. In connection with alternative formulations or other changes to any of our product candidates, the FDA and other regulatory authorities may require additional studies, including bridging studies, which may significantly delay our clinical trial timelines and potential regulatory approval.

We have concentrated our recent 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 brain disorders is extremely difficult and is subject to a number of unique challenges. In addition, our 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 brain 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 PD, 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 US Developing a product candidate for treatment of these brain diseases is extremely difficult and subjects us 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.

Our 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 we 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, we cannot be certain that our approach will lead to the development of approvable or marketable products. To date, 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 us or others may result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect our business and the market price of our common stock.

Clinical results observed in our Phase 1, Phase 2 and open-label clinical trials, including the 16-week Extension phase data from the RewinD-LB Trial, evaluating neflamapimod are not regulatory evidence of drug safety or efficacy.

Data results from our non-Phase 3 studies do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for neflamapimod in DLB or any other indication. Rigorous evidence for drug safety and efficacy is derived from one or more large, randomized, placebo-controlled studies. The size and open-label design of portions of our non-Phase 3 studies may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. Different methods of statistical analysis on clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our non-Phase 3 studies add complexity or limitations to the scope of data interpretation.

In addition, conclusions based on data from analyses of Phase 1 and Phase 2 clinical studies and open-label results may not be reproduced when implemented in large, well-controlled, randomized clinical trials. Particular caution should be exercised when interpreting preliminary data, data relating to a small number of patients and data from open-label uncontrolled studies, which are generally not capable of providing interpretable evidence of efficacy. There can be no assurance that future large, well-controlled, multi-dose studies will demonstrate the safety, tolerability or efficacy of neflamapimod to treat patients with any indication, including DLB.

Even if our clinical trials for neflamapimod are completed as planned, we cannot be certain that their results will support the substantial evidence of safety and efficacy needed to obtain regulatory approval. The failure of neflamapimod to show safety, tolerability or efficacy in any future clinical studies would significantly harm our business.

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 our control.

The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of research participants who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of individuals to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of participants to complete any of our 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;

- Our 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 US 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 MA, 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. 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. 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 we 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 may result in increased costs or program delays, which could have a harmful effect on our ability to develop a product candidate or could render further development impossible.

Results of nonclinical studies, early clinical trials, and analyses of open-label results, including the Extension Phase results from the RewinD-LB Trial, may not be indicative of results obtained in later large, well-controlled, randomized clinical trials. In addition, preliminary, topline and interim data from our clinical trials that we 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 nonclinical 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 nonclinical 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 our clinical trials for neflamapimod are completed as planned, including any future Phase 3 trial, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval, and we may decide, or regulators may require it, to conduct additional clinical trials.

In addition, from time-to-time, we may announce or publish preliminary, topline, or interim data from our 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, which may prove to be incomplete or flawed, and we 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 we 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 our business prospects.

Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical 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 our 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 we in general.

In addition, the information we choose 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 we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine 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 our business. If the interim, preliminary, or topline data that we report differ from later, final or actual results, or if others, including the FDA and comparable foreign regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and, if approved, commercialize our product candidates may be harmed, which could harm our 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.

We have in the past and may in the future conduct additional clinical trials evaluating our product candidates, including neflamapimod, outside the US The acceptance of trial data from clinical trials conducted outside the US by the FDA may be subject to certain conditions or may not be accepted at all, and other comparable non-US regulatory authorities may have similar restrictions and conditions with respect to clinical trials conducted outside of their jurisdiction. In cases where data from non-US clinical trials are intended to serve as the basis for marketing approval in the US and the trial is not conducted under the IND, the FDA will generally not accept such foreign trial data unless: (i) the data are determined to be applicable to the US population and US 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-US regulatory authorities have similar approval requirements.

There can be no assurance that the FDA will accept data from trials conducted outside of the US or that any comparable non-US regulatory authority will accept data form trials conducted outside of the applicable jurisdiction. If the FDA or any comparable non-US 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 US may also expose us 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.

In August 2024, we initiated a Phase 2a study in Strasbourg, France, to evaluate a twice daily regimen (80mg BID) of neflamapimod in up to 25 patients with DLB with MCI (MoCA score $\geq$ 18 during screening). The primary objective of the study is to obtain additional PK data on a dosing regimen not previously used in any of our clinical trials (80mg BID) that is above the maximum dosage currently permitted by the FDA's partial clinical hold on neflamapimod. If it is determined that the 80mg BID dosing regimen is safe and tolerable, we may in the future seek to use data from this trial to support an application to increase neflamapimod's no adverse event level and remove the existing partial clinical hold. However, because this data is being obtained from a trial conducted outside of the US, it is possible the FDA will not accept such data.

Safety issues with neflamapimod or with any other product candidate we may develop or acquire in the future, or with product candidates or approved products of third parties that are similar to our 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 us to modify or supplement our clinical development program.

Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. SAEs or undesirable side effects caused by neflamapimod, or any other product candidates we 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 shown 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 ours could adversely affect the development, regulatory approval and commercialization of our product candidates.

For example, to date, neflamapimod has been evaluated in over 550 participants, at doses up to 750mg twice a day, and up to 32 weeks of treatment. The adverse effects seen in more than 5% of neflamapimod-treated participants in completed trials, which include headache, diarrhea, abdominal pain, respiratory infection, and falls, were generally mild. 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 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 RA, elevations in such liver enzymes levels were noted in six subjects (14%).

After we acquired an exclusive license from Vertex to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders, we submitted an IND application to the DNP in February 2015. The DNP cleared our 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 our 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. Our current understanding of plasma drug levels achieved with neflamapimod in humans means that our investigational dosing in the US is limited by this partial clinical hold to no more than 40mg TID in patients weighing 50 kg (110 lbs.) or more.)

With respect to the adverse effects discussed above, the participants 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 we continue 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 our clinical trials for neflamapimod in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of our 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. On the other hand, many drugs provide superior efficacy at higher doses and, if determined to be safe and tolerable, higher doses of neflamapimod may be desirable for a variety of reasons. Accordingly, we are currently undertaking a number of studies, including our Phase 2a DLB trial in Strasbourg, France, and several nonclinical studies, to further evaluate the safety and tolerability profile of higher doses of neflamapimod, including 80mg BID.

If we 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 us 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 we 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 us to take our drug off the market. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials, by their nature, utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of neflamapimod or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If neflamapimod, or any other product candidates we may develop or acquire, receives marketing approval and we 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;

- we 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;

- we may be subject to regulatory investigations and government enforcement actions;

- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;

- we may decide to recall such product candidates from the marketplace after they are approved;

- we could be sued and held liable for injury caused to individuals exposed to or taking its product candidates; and

- our reputation may suffer.

We may be unable to obtain regulatory approval in the US or foreign jurisdictions and, as a result, be unable to commercialize our product candidates and our 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 CMC, nonclinical 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 US, 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 US, 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 we seek to enter into collaborative arrangements or strategic alliances for our drug candidates, but fails to enter into and maintain successful relationships, we may have to reduce or delay our drug development activities or increase our expenditures.

An important element of a biotechnology company's strategy for developing, manufacturing and commercializing our drug candidates may be to enter into strategic alliances with pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. Biotechnology companies at our 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, we have not entered into any collaborative arrangements or strategic alliances, and we may face significant competition in seeking such relationships. In addition, such arrangements may place the development of our drug candidates outside our control, require us to relinquish important rights, or may otherwise be on terms unfavorable to us. We may not be able to negotiate collaborations and alliances on acceptable terms, if at all. If we enter into a collaborative arrangement and it proves to be unsuccessful, we may have to delay, or limit the size or scope of, certain of our drug development activities.

Alternatively, if we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may not be available to us on acceptable terms, if at all.

If we are unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, our 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 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 we 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 our 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. Our inability to fully take advantage of these programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, and incur greater expense in the development of our product candidates.

The FDA granted orphan drug designation for neflamapimod for certain indications, which might not provide the intended benefit thereof.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug product if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the US In November 2024, we received orphan designation from the FDA for neflamapimod for the treatment of frontotemporal dementia. There is no guarantee that neflamapimod will be successfully approved by the FDA for such indication, neflamapimod will be commercially successful for such indication in the marketplace, if approved, or that another product will not be approved for the same indication ahead of neflamapimod.

Even if we obtain orphan product exclusivity for neflamapimod for the treatment of FTD, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an orphan drug product is approved, the FDA can subsequently approve another drug or biologic for the same disease or condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, orphan product exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, our business will be harmed.

Although we design and manages our nonclinical studies and clinical trials, we have a limited number of employees and do not currently have the ability to conduct clinical trials for neflamapimod on our own. We have 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 our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, as well as legal and regulatory and scientific standards. We have limited control over these third parties, and they

may not devote sufficient time and resources to our 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 our applications for filing. There is no assurance that the third parties we engage 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 our requisite quality standards, including due to geopolitical events, natural disasters, public health emergencies or pandemics, or poor workforce relations or human capital management.

We and our CROs are required to comply with GLP requirements for nonclinical studies and GCP requirements for clinical trials, which are regulations and guidelines enforced by the FDA and required by comparable foreign regulatory authorities. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving marketing applications for our product candidates. There is also no assurance these third parties will not make errors in the design, management or retention of our 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 our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develops. As a result, our financial results and the commercial prospects for neflamapimod would be harmed, our costs could increase, and our ability to generate revenue could be delayed, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have employed several different CROs for clinical trial services. Although we believe there are numerous alternatives to provide these services, in the event that we seek a new CRO, we 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 we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

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

We have no manufacturing facilities and do not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. We currently rely on third parties for the manufacture of DS, the manufacture of DP, and the packaging of DP for clinical use. This reliance on CMOs and suppliers subjects us 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.

We further intend to rely on third-party CMOs for the production of commercial supply of neflamapimod if it is ultimately approved. If CMOs cannot successfully manufacture DS and DP for our neflamapimod program, or any other product candidate that we may develop or acquire in the future, in conformity to its specifications and the applicable regulatory requirements, we 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 we experience with any such CMOs could delay the manufacturing of our product candidates, which could harm our results of operations. All drug manufacturers and packagers are required to operate in accordance with FDA-mandated cGMPs. The failure of any of our current or future CMOs to establish and follow adequate procedures to ensure compliance with applicable cGMP requirements 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 our product candidates into the market. In the event of such failure, we 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, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to obtain regulatory approval for or commercialize neflamapimod.

In addition, if any facility of our 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, we could be materially adversely affected and any of our clinical trials could be materially delayed. An extended shutdown may force us to procure a new research and development facility or another manufacturer or supplier, which could be time-consuming.

Our RewinD-LB Trial was conducted with a DS previously manufactured at a third-party CMO. Future supplies of the neflamapimod DS 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. During this period, we may be unable to receive investigational neflamapimod supplies or any other product candidates we may develop or acquire. In addition, a disruption in the supply of DS could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost-effectively manufacture our product candidates.

We also currently rely on a third-party CMO (different than that for the DS) for the manufacture of neflamapimod DP. We have used the same manufacturer for our neflamapimod DP 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 DP. 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 DS or DP with our current manufacturing providers, or with any alternate manufacturers.

While we believe that there are multiple alternative sources available for manufacturing of both DS and DP in our neflamapimod program, we may not be able to enter into replacement arrangements, on acceptable terms or at all, without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

Although we generally have not, and do not intend to, begin a clinical trial unless we believe we had 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 DS or DP could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

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

If we change the manufacturers of our product candidates, we may be required to conduct comparability studies evaluating the manufacturing processes of the product candidates and incur other costs related to the technology transfer.

The FDA and other regulatory agencies maintain strict requirements governing the manufacturing process for prescription DPs that would apply to our 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 we were to change manufacturers of our DS or DP during or after the clinical trials and regulatory approval process for neflamapimod or any of our other product candidates, we 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 DP 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 DP, 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 DP'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. For example, if we decide to utilize a different CMO to manufacture future DS batches, certain compatibility studies may be required, and we may incur additional costs related to the technology transfer.

Delays in designing and completing a comparability study to the satisfaction of the FDA or other regulatory agencies could delay or preclude our development plans and, thereby, delay our ability to receive marketing approval or limit our revenue and growth, once approved. In addition, in the event that the FDA or other regulatory agencies do not accept nonclinical comparability data, we 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 our product candidates.

Risks Related to Our Intellectual Property

If we do not adequately protect our proprietary rights, we may not be able to compete effectively.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to neflamapimod. Our commercial success depends in part on obtaining and maintaining proprietary rights in the US and in international jurisdictions and successfully defending these rights against third-party challenges if and as they occur. We seek to protect our proprietary position by filing patent applications related to neflamapimod in the US and in other countries.

Although we have already obtained several issued patents and are working to expand our estate with additional patent applications, third parties may challenge the validity, enforceability, or scope of our 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 us could deprive us of rights necessary for the successful commercialization of neflamapimod, or any other product candidates we may develop. Further, if we encounter delays in regulatory approvals due to patent-related issues, the period of time during which we could market a product candidate under patent protection could be reduced.

Our issued patents and patent applications also remain subject to uncertainty and continued monitoring. Our patent applications may fail to result in issued patents with claims that provide further coverage for neflamapimod in the US or in foreign countries. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify further patentable aspects of our 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 our 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 US and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether it was the first to make the inventions claimed in our 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 our inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the US 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 our 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 our patents, requiring us 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 our products.

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

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

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

We 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, nonclinical and clinical data, and certain specified Vertex patent rights, including a composition of matter patent for neflamapimod that expired in 2017. We have thus focused our 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 PK and processes for the manufacture thereof. In the US, 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, our 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. We own a patent that is issued in the US around co-crystals of neflamapimod, any of which if they were successfully developed would be afforded composition of matter patent protection under this patent.

Accordingly, the lack of composition of matter patent protection that covers neflamapimod may subject us 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 our business, financial condition or results of operations.

If we fail to comply with our obligations under our existing license agreement with Vertex, or with any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are party to the Vertex Agreement pursuant to which we 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, we 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 our 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, 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 our rights to neflamapimod and could compromise our development and commercialization efforts. This in turn would have an adverse effect on our business, which could be material.

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

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our lead product candidate, neflamapimod, without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Some claimants may

have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than us. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us in the future. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We 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 we believe 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 our ability to commercialize our applicable product candidate unless we 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 our 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 ours.

As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us 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 our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

Finally, even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our 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 our reputation, harm our business, and the price of our common stock could be adversely affected.

We 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 our ability to develop, manufacture and market our product candidates.

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

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

Competitors may infringe our patents or other intellectual property or the intellectual property of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our 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 our 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 our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our 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 our 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, our patents or patent applications. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer we a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Even if we establish 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 our 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, we could have a substantial adverse effect on the price of our common stock.

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

Our success is heavily dependent on intellectual property, particularly patents, and obtaining and enforcing patents in our industry involves both technological and legal complexity. Changes in either the patent laws or interpretation of the patent laws in the US and other countries may diminish the value of our patents or narrow the scope of our patent protection.

For example, the AIA, which was passed in September 2011, resulted in significant changes to the US patent system. Pursuant to the AIA, the US 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 we could therefore be awarded a patent covering our invention even if we made the invention before it was made by the third party. This requires us 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 US 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 our patent applications and the enforcement or defense of our issued patents.

In addition, the laws of other countries may not protect our rights to the same extent as the laws of the US The complexity and uncertainty of European patent laws have 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 our ability to obtain new patents in the future, which may be important for our business.

We enjoy only limited geographical protection with respect to certain patents, and we may not be able to protect our intellectual property rights throughout the world.

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

Although we intend to seek protection of our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. We 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 us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, 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 we are forced to grant a license to any third parties with respect to any patents relevant to our business, our competitive position may be impaired.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. For example, in the US, 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 our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. The launch of a generic version of one of our 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 our business, financial condition, results of operations and prospects. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to our product candidates. In addition, although upon issuance in the US 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 US 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, we may not receive an extension if we 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 we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and nonclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. If we do not have sufficient patent life to protect our products, our 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 US-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-US manufacturers.

We received the NIA Grant to support our RewinD-LB Trial. Pursuant to the Bayh-Dole Act, the US government may have certain rights in any invention developed or reduced to practice with this funding. In addition, in the future we may discover, develop, acquire, or license intellectual property that has been generated through the use of US government funding or grants in which the US government may have certain rights pursuant to the Bayh-Dole Act. These US government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the US government has the right, under certain limited circumstances, to require us 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 US government exercises its march-in rights in our intellectual property rights that are generated through the use of US government funding or grants, we could be required to license or sublicense intellectual property discovered or developed by it or that it licenses on terms unfavorable to us, and there can be no assurance that we would receive compensation from the US government for the exercise of such rights. The US 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 us to expend substantial resources. Should any of these events occur, it could significantly harm our business, results of operations and prospects. In addition, the US 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 US This preference for US 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 US or that under the circumstances domestic manufacture is not commercially feasible. This preference for US industry may limit our ability to contract with non-US product manufacturers for products covered by such intellectual property.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our 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.

We may rely on trade secrets or confidential know-how to protect various aspects of our business, especially where patent protection is believed by us to be of limited value. Due to our reliance on third parties in various aspects of our business, including CMC, research and development, and collaborations, we must, at times, share trade secrets with such parties. We may also conduct joint research and development programs that require us to share trade secrets under the terms of our 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, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our 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 our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets could impair our competitive position and have an adverse impact on our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our 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 we own or have exclusively licensed;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- we may not develop additional proprietary technologies that are patentable;
- we 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;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our 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, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Risks Related to Commercialization

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We have not yet demonstrated, either on our 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 our future success or viability may not be as accurate as they may be if we 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, we may encounter unforeseen expenses, complications, delays and other known and unknown factors. If we are able to successfully develop neflamapimod, we may eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

As we continue to build our business, we expect that our 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 our control. Accordingly, investors should not rely upon the results of any particular quarterly or annual period as indications of our future operating performance.

Our business operations are subject to applicable healthcare laws and regulations. If neflamapimod is approved, we will also be subject to stringent regulation and ongoing regulatory obligations and restrictions, which could delay our marketing and commercialization activities and also expose us to penalties if we fail to comply with applicable regulations.

Although we do not currently have any products on the market, once we begin commercializing neflamapimod or any other future product candidates, we 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 we conduct our 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 we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Among others, restrictions under applicable domestic and foreign healthcare laws and regulations include:

- the US 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;

- US federal false claims, false statements and civil monetary penalties laws, including the FCA, 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 US 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;

- US 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 our 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 us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our 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 our product candidates, we 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 our 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 our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we 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 our operations. If any of the physicians or other healthcare providers or entities with whom we expect 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 we develop receives marketing approval, we may fail to achieve the level of acceptance necessary for commercial success.

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

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

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various CNS and neurodegenerative indications, in particular DLB. The addressable patient populations that may benefit from treatment with our product candidates, if approved, are based on our 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 our product candidates would be limited to the therapeutic indications examined in our clinical trials and as determined by the FDA, which would not permit us to market our products for any other therapeutic indications not expressly reviewed and approved as safe and effective. In DLB, in particular, prevalence estimates among experts and practitioners vary greatly, as do estimates of the percentage of DLB patients that have AD co-pathology.

Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Even if we receive regulatory approval for any of our product candidates, such approval could be conditioned upon label restrictions that materially limit the addressable patient population. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

We face substantial competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. If neflamapimod is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies, biopharmaceutical companies in the US and other jurisdictions, academic institutions and governmental agencies and public and private research institutions. These organizations may have significantly greater resources than we do. 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 developing treatments specifically 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, we anticipate that more companies will enter the DLB market in the future. Our 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 we may obtain approval for neflamapimod, which could result in their establishing or strengthening a commercial position before we are 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 our ability to advance neflamapimod commercially. If we are unable to compete effectively, this could have a material adverse effect on our business and results of operations.

The successful commercialization of neflamapimod, or any other product candidate we may develop or acquire, depends 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 us to obtain marketing approval of and commercialize our product candidates, if approved, and also affect the prices we may set. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

There have been, and we expect will continue to be, a number of legislative and regulatory proposals and changes to the healthcare systems in the US and other jurisdictions that could affect our future results of operations. In particular, a number of initiatives at the US 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 we may develop or acquire. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the US or abroad. 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 may have obtained, and we may not achieve or sustain profitability.

In the US, 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. Our 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 our ability to successfully commercialize neflamapimod and any other potential future product candidates. Assuming we obtain 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. We cannot be sure that coverage, payment, and reimbursement in the US or elsewhere will be available for any drug product that we 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 US to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, healthcare, which includes initiatives to reduce the cost of healthcare. For example, in March 2010, the US Congress enacted the ACA, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the US 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 US

In August 2022, the IRA was signed into law, 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 US 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 our impact on our 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 US 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 FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry, prompting further legislative and regulatory actions and litigation. In particular, several PBM regulatory reforms became law in February 2026, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only *bona fide* service fees from drug companies when providing services under Medicare Part D. The Department of Labor also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under ERISA and would allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. 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 US, we may also be subject to extensive governmental price controls and other market regulations in those countries. Governments outside of the US, 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, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, recent US federal government actions include initiatives incorporating most-favored-nation (international reference pricing) concepts for certain prescription drugs, as well as agency testing of new payment models that could tie Medicare reimbursement or manufacturer rebates to prices in specified reference countries with strict price controls. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. As a result, we might obtain regulatory approval for a product in a particular country but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in our product candidates, even after obtaining regulatory approval.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the US or any other jurisdiction. In the US, 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 us from being able to generate revenue, attain profitability or commercialize our product candidates. Further, if we or any third parties with whom we engages in the future are slow or unable to adapt to changes in existing requirements or policies, or if we are not able to maintain regulatory compliance, our 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 we are unable to obtain adequate coverage and payment levels for our 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 our ability to successfully commercialize any approved products and thereby adversely impact our profitability, results of operations, and financial condition.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing neflamapimod, if approved.

We do 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, we must build our 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 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.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with others, we will not be successful in commercializing neflamapimod, if it is ultimately approved, and it may never become profitable. We 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, we may be unable to compete successfully against these more established companies.

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

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

Although we currently have limited product liability insurance that covers our clinical trials, we will need to increase and expand this coverage as we commence 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 our 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 our business and results of operations.

Any product candidate for which we obtain 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 we may be subject to penalties if we fail to comply with regulatory requirements or if we experiences unanticipated problems with our products, when and if any of them are approved.

If the FDA or a comparable foreign regulatory authority approves neflamapimod or any of our 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 we 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 us. If we or our third-party providers, including our CMOs, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain 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, we will not be able to promote any products we develop 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 we promote our products beyond their approved indications, we 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 we receive marketing approval for neflamapimod, we and our 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 we are not able to comply with post-approval regulatory requirements, we could have marketing approval for any of our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our 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 our product 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 may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Risks Related to Our Securities

Our stock price may be volatile, there may be limited liquidity in the trading market for our common stock, and the market price of our common stock may drop in the future.

The market price of our 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 our common stock to fluctuate include, among others:

- the ability of us or our partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of us or our partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure by us to maintain our existing third-party license, manufacturing and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our 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 our competitors;
- failure to meet or exceed financial and development projections we 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 us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our 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 us, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;

- the limited percentage of our outstanding shares that are currently freely tradeable as a result of the significant holdings of our directors and officers;
- adverse publicity relating to our 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 our financial results.

Accordingly, the market price of our common stock may be highly volatile and could fluctuate widely in price as a result of these or other factors. In particular, we have relatively few shares of common stock outstanding in the "public float" as a higher percentage of our 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 our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our 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 our securities. We may in the future be the target of similar litigation if our stock continues to experience price volatility. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

We have funded our 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 we will need to raise additional capital through similar means to fund our 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 our existing stockholders and could depress the market price of our 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.

We will likely need to raise additional funds in the future to continue our operations, fund research and development, and, if approved, commercialize our product candidates. We currently plan 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 we believe the terms are in the best interests of our stockholders. In addition, we 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 us or holders of a large number of shares could reduce the market price of our common stock, including in connection with the exercise of any Series A Warrants issued in connection with the 2024 Private Placement. We 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 our common stock. Furthermore, a depressed stock price could limit our ability to raise necessary capital through the sale of additional equity securities on terms that are acceptable.

Ownership of our common stock is highly concentrated among our officers and directors, which may prevent our stockholders from influencing significant corporate decisions and may result in perceived conflicts of interest that could cause us stock price to decline.

As of March 11, 2026, our executive officers and directors owned, directly or indirectly, approximately 32.0% of the outstanding shares of our 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 us asset or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of ours, even if such a change of control would benefit the other stockholders of ours. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing stockholders of ours sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after certain legal and contractual restrictions on resale lapse, the trading price of our common stock of us could decline.

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

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

If we cannot continue to satisfy the Nasdaq Capital Market continued listing standards and other Nasdaq rules, our common stock could be delisted, which could harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock.

Our common stock is currently listed on the Nasdaq Capital Market. To maintain this listing, we are required to meet certain listing requirements related to, among other things, the trading price of our common stock, our market capitalization and certain corporate governance-related requirements. In the event our 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 our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult for us to raise capital and for our stockholders to dispose of, or obtain accurate price quotations for, our common stock. There would likely also be a decline in the liquidity of the trading market for our common stock and a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

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

Provisions in our certificate of incorporation, as amended, and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our 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 our common stock, thereby depressing the market price of our common stock. In addition, because the Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our 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 our 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 our stockholder's 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 our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation, as amended, or for stockholders to amend or repeal our amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are 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.

Our 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 our stockholders, which could discourage lawsuits against us and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent 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 our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to the Company or our 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 our 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 our stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction, and may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

Our current expectation is that we will retain future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, will be your sole source of potential gain on an investment in our common stock for the foreseeable future.

General Risks Related to Our Business and Operations

AI presents risks and challenges that can impact our business including by posing security risks to confidential information, proprietary information, and personal data, as well as emerging, unknown business risks.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. We may adopt and integrate generative AI tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative AI tools into their offerings, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. Additionally, AI algorithms may be flawed, datasets may be insufficient or biased, and ineffective AI development or deployment could lead to other compliance violations. While we have implemented controls intended to, among other things, limit the risk that proprietary or confidential information is used to train AI models, no such controls can completely eliminate the inherent risks associated with AI. If we, our vendors, or our third-party partners experience an actual or perceived violation of applicable privacy or data protection, intellectual property, or other laws or regulations, or a cybersecurity incident due to the use of generative AI, we could be subject to regulatory fines, investigations, enforcement actions, penalties and other liabilities, claims for damages from affected individuals, and we may lose valuable intellectual property and confidential information, including the risk that AI-generated outputs may infringe third-party intellectual property, and our reputation and the public perception of the effectiveness of our privacy or cybersecurity measures could be harmed. Additionally, potential future

overreliance on AI or dependence on a specific model or vendor could limit our flexibility, increase costs, or expose us to operational risks if the AI provider modifies or discontinues its services, or experiences service interruptions or security incidents. Several jurisdictions around the globe, including Europe and the US, have already proposed or enacted laws governing AI, and we may need to commit significant resources to maintain business practices that comply with the evolving regulatory landscape. Our competitors or other third parties may incorporate AI into their products more quickly and successfully than we, which could impair our ability to compete effectively and adversely affect our results of operations. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business. For example, our approach to the treatment of DLB focuses in large part on neflamapimod's ability to inhibit the intra-cellular enzyme p38α. Through the use of AI and large language models, competitors could seek to identify alternative p38α inhibiting compounds and repurpose those assets to compete with neflamapimod in the future.

The development and use of AI presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information, and personal data and could give rise to legal and/or regulatory actions, damage our reputation, or otherwise materially harm our business.

AI is increasingly being used in the biopharmaceutical, pharmaceutical, technology, and consumer health industries. We evaluate different AI technologies and identify areas where we can apply AI to improve our operations. Issues relating to the use of new and evolving technologies such as AI, machine learning, generative AI, and large language models, may cause us to experience perceived or actual brand or reputational harm, technical harm, competitive harm, legal liability, cybersecurity risks, privacy risks, compliance risks, security risks, ethical issues, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. In addition, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with US and non-US laws concerning the use of AI, the nature of which cannot be determined at this time. For example, the European Union recently passed the Artificial Intelligence Act, whose regulations will be developed over the coming year and, in the United States, the recent Executive Order concerning AI may result in extensive new federal rule-making. Further, market demand and acceptance of AI technologies are uncertain, and we may be unsuccessful in our product development efforts.

As necessary, we have developed policies governing the use of AI to encourage appropriate use of AI by our employees, contractors, and authorized agents and that our assets, including intellectual property, competitive information, personal information we may collect or process, and customer information, are protected. Any failure by our personnel, contractors, or other agents to adhere to any policies that we may establish could violate confidentiality obligations or applicable laws and regulations, jeopardize our intellectual property rights, cause or contribute to unlawful discrimination, or result in the misuse of personally identifiable information or the injection of malware into our systems, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Our future success depends in large part on our ability to retain our key employees, as well as our ability to attract, train and motivate additional qualified personnel. We may also encounter difficulties in managing our growth, which could disrupt our operations.

We have a small number of employees, and we are highly dependent on the principal members of our management team, including our President and Chief Executive Officer, John Alam, M.D. Although we have employment agreements or offer letters with our 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 our headquarters are located. We also face competition for the hiring of scientific and clinical personnel from universities and research institutions, many of which are near our headquarters. The loss of the services of any member of our 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 our business, operating results and financial condition.

We also rely on consultants and advisors to assist us in formulating and executing our business strategy. Many of our 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 us.

As we continue to develop neflamapimod, we expect to experience significant growth in the number of employees and the scope of our operations. This strategy will require us to recruit additional clinical development, regulatory, scientific, and technical personnel, as well as sales and marketing personnel if neflamapimod is approved. If we are unable to attract, retain and motivate a sufficient number of highly qualified personnel to match such growth, our ability to further develop and commercialize neflamapimod, or any future product candidates we may develop or acquire, will be limited.

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

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are 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 we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

However, we believe 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.

In the future, we could identify one or more material weaknesses in our control environment. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. The identified material weaknesses, if not corrected, could result in a material misstatement to our consolidated financial statements that may not be prevented or detected. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements.

For example, in connection with the audit of our financial statements for the years ended December 31, 2024, 2023 and 2022, material weaknesses in our internal control over financial reporting were identified related to the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts. We may identify additional material weaknesses in our internal controls over financing reporting in the future which we 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 we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. More generally, any failure by us to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and could cause us to fail to meet our reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock.

Our IT systems, or those of our 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 our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of our business, we collect and store 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. We face risks related to protecting this critical information including loss of access, unauthorized disclosure, unauthorized modification, and inadequate monitoring of our controls over these risks. We also rely on IT systems and networks, including third-party "cloud-based" service providers, and our third-party CROs, to process, transmit and store electronic information in connection with our 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 our systems and networks and the confidentiality, availability and integrity of our 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, we may be unable to anticipate these techniques or implement adequate preventative measures.

Despite the implementation of security measures, our internal IT systems and those of our 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. Additionally, developments in AI and machine learning provide threat actors with the capability to use more sophisticated means to attack our systems and may exacerbate cybersecurity risk. These threats pose a risk to the security of our IT systems and networks and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in detecting or preventing cybersecurity incidents, or successfully mitigating their effects. As a result, we may experience cybersecurity incidents that may remain undetected for an extended period.

Any such disruption or security incident could cause interruptions to our operations and result in disruption of our development programs and business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. A successful cyberattack could also cause misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. If we were to experience a significant cybersecurity incident that impacts our 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, our 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, our recently increased remote workforce could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruption.

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

Our business may be affected from time to time by government investigations and litigation with third parties, including our ongoing matter with Paul Feller.

We 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 our 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 our business, financial condition, results of operations and prospects.

For example, in August 2014, Paul Feller, the former Chief Executive Officer of our legal predecessor, filed a complaint asserting various causes of action related to his past affiliations with our legal predecessor. While we are defending itself vigorously against the claims alleged in this matter, we are 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 our financial position. Depending on the outcome or resolution of this matter, it could have a material effect on our consolidated financial position, results of operations and cash flows.

Our business is, or may in the future become, subject to complex and evolving US and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business.

The global data protection landscape is rapidly evolving, and we are currently and may become subject to or impacted by a wide variety of provincial, state, national, and international laws and regulations applying 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. Implementation standards and enforcement practices are likely to remain uncertain and unpredictable for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. 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.

In the US, 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. For example, 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 uncertainty about how provisions of the CCPA and the new regulations will be interpreted and how the law will be enforced. In addition to California, more US states have enacted and are continuing to enact similar legislation, increasing compliance complexity and increasing risks of failures to comply. The existence of differing comprehensive privacy laws in different states in the country may make our compliance obligations more complex and costly and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice), may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The FTC and states' Attorneys Generals have brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

In addition, other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington state passed the "My Health My Data" Act, which came into force in 2024 and regulates "consumer health data," which is broadly defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data" Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C.F.R. Parts 46, 50 and 56. Notably, the "My Health My Data" Act contains a private right of action. In addition, Nevada enacted a consumer health data privacy bill, SB 370, which took effect in 2024, and regulates "consumer health data." SB 370 shares many similarities with Washington's "My Health My Data" Act, and Connecticut has amended its comprehensive privacy law to include heightened regulation of "consumer health data." Furthermore, several states, including Illinois, Texas, and Washington, have enacted biometric privacy laws that regulate the collection and use of biometric identifiers, which may be relevant to certain activities or research involving biometric data. Additional states are considering and may adopt health-specific privacy laws that could impact our business activities and our collection and handling of health-related data.

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 US The GDPR imposes stringent data protection requirements and provides penalties for noncompliance of up to the greater of €20 million or four percent of worldwide annual turnover. 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 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 our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we may operate in. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Ensuring our continued compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Many jurisdictions outside of US 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.

Additionally, following the United Kingdom's withdrawal from the European Union (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover.

Transfers of personal data to certain countries outside of the EEA and the UK are also highly regulated under the GDPR and UK GDPR. For example, the GDPR only permits exports of personal data outside of the EEA to "non-adequate" countries where there is a suitable data transfer mechanism in place to safeguard personal data (e.g., the European Commission approved Standard Contractual Clauses or certification under European Union-US the Data Privacy Framework). On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EEA to the certain US organizations, the EU-US 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 transfers of personal data from the European Union to the US. Notably, the new obligations were geared to ensure that data can be accessed by US intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the US 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. Additionally, the Data Privacy Framework may be subject to legal challenges, and there can be no assurance that it will remain a valid transfer mechanism. Prior transfer frameworks, including the European Union-US Privacy Shield, were invalidated by the Court of Justice of the European Union in its July 2020 decision in Maximilian Schrems vs. Facebook (Case C-311/18) (Schrems II), which also heightened the burden on companies to assess US national security laws and implement supplementary measures when relying on

standard contractual clauses. Consequently, there is some risk that data transfers from the EEA could be challenged or halted. Future actions of European Union 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 laws in the US 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 our 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, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our 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 our reputation, inhibit our ability to conduct trials, and adversely affect our business.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws or to protect personal data or other data we process or maintain may expose us 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 we are found to be non-compliant, and damage to our reputation, any of which could materially affect our 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 our business and reputation.

Past or future transactions resulting in an ownership change under Section 382 may subject our NOL carryforwards and certain other tax attributes to limitation.

As of December 31, 2025, we had US federal NOL carryforwards of approximately $16.6 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 we are a party may, alone or in the aggregate, result in such an ownership change and, accordingly, our NOL carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use in the future. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our 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, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

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

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

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, 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-US 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. Our business is heavily regulated and therefore

involves significant interaction with public officials, including officials of non-US 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 of our dealings with these prescribers and purchasers are subject to regulation under the FCPA. There is no certainty that all our employees, agents, contractors, or collaborators, or those of our 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 us, our officers, or our 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 our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, future international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. However, in February 2025, President Trump issued an executive order directing the Department of Justice to pause enforcement of the FCPA and to issue new enforcement guidelines that take into consideration US national security and the competitiveness of US companies abroad. It is unclear how, if at all, this presidential directive may affect the pharmaceutical industry as a whole or our business in particular.

Our 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.

We are exposed to the risk of fraud, misconduct or other illegal activity by our 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 we have established; comply with healthcare fraud and abuse laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products, our potential exposure under such laws will increase significantly, and our 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 our reputation. We have 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 we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us 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 us, and we are not successful in defending itself or asserting our rights, those actions could have a significant impact on our 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 ours business may rely, which could negatively impact our 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, our 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 our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the FDA has experienced significant and rapid fluctuations in leadership and scientific review personnel, which may be key contributing factors in multiple reported delays in agency decision making on marketing applications and agency requests for additional data that are inconsistent with prior regulatory feedback. Additionally, the next FDA user fee reauthorization package entered stakeholder negotiations in mid-2025, and any agreement is expected to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program must be finalized by

Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry.

In addition, government funding of the SEC and other government agencies on which our 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 slow the time necessary for clinical trial applications and/or marketing applications for new drugs to be reviewed or approved, which would adversely affect our business. For example, political disputes in Congress may result in a shutdown of the US government and, in such cases, certain regulatory agencies, such as the FDA and the SEC, may have to furlough critical staff and stop critical activities. Government shutdowns or slowdowns can increase the time needed for an agency to complete its review or make final approvals or other administrative decisions. If a prolonged government or slowdown shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and the ability of the SEC to timely review our public filings, to the extent such review is necessary, and our ability to access the public markets, each of which could have a material adverse effect on our business.

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

US federal income tax reform or other changes in applicable tax law could adversely affect our business and financial condition.

The rules dealing with US federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the US 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 US economy in response to the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of NOLs, 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 our 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, we may be required to pay federal income tax in some future year notwithstanding that we 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 our business, cash flow, financial condition or results of operations.

We face risks associated with increased geopolitical uncertainty, including as a result of evolving domestic and foreign tariff policies.

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 US 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 our business, financial condition and results of our operations.

In addition, the Trump administration has signaled intentions to substantially alter prior US government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. Further, President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the US to accomplish certain US policy goals. On April 2, 2025, a universal 10% tariff on all US imports was announced, with higher tariffs ranging from 11% to 50% on imports from 57 countries. Tariff rates have since fluctuated as a result of bilateral negotiations and legal challenges, and product-specific tariffs have also been implemented. On February 20, 2026, the US Supreme Court ruled against the Trump administration's

use of tariffs under the IEEPA and US Customs and Border Protection halted collections of IEEPA tariffs on February 24, 2026. However, the decision creates uncertainty related to various aspects of the tariffs previously collected under the IEEPA, including whether, and if so, how, companies may be able to recover any portion of IEEPA tariffs previously paid. Additionally, in response to the US Supreme Court ruling, the Trump administration imposed a new worldwide tariff effective for 150 days from February 24, 2026. These ongoing measures have led to retaliatory tariffs from affected countries and have contributed to increased trade tensions and economic uncertainty. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our operations, disrupt our supply chain and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the US' or other countries' trading relationships or the impact of new laws or regulations adopted by the US or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition, results of operations and cash flows.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our 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 US and international markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Epidemics, pandemics or other public health crises, including COVID-19, could adversely affect our business.

Our operations could be significantly adversely affected by the effects of a widespread outbreak of epidemics, pandemics or other health crises, including COVID-19. We 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 us, 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 our operations and ability to finance our operations.

Political uncertainty may have an adverse impact on our operating performance and results of operations.

General political uncertainty may have an adverse impact on our operating performance and results of operations. In particular, the US continues to experience significant political events that cast uncertainty on global financial and economic markets. It is presently unclear exactly what actions our current administration in the US will implement, and if implemented, how these actions may impact the pharmaceutical industry in the US

We hold our cash and cash equivalents that we use to meet our working capital needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold our cash and cash equivalents that we use 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 we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we 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 our short-term liquidity and ability to meet our 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 US Department of the Treasury, the Federal Reserve and the FDIC. While we did not hold any of our funds in accounts with either of these institutions, if financial institutions in which we hold funds for working capital were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

We may also, from time to time, maintain investment accounts with other financial institutions in which we holds our investments and, if access to the funds we use for working capital is impaired, we may not be able to sell investments or transfer funds from our 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 our working capital needs.

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

One or more of our stockholders may from time to time seek to acquire a significant or controlling stake in us, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes to our 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 our operations and divert the attention of our Board and senior management, and could adversely affect our operations, financial condition, and the value of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management Program Overview

We recognize the critical role that properly managing cybersecurity risk plays in maintaining the trust and confidence of our stockholders, the patients in our clinical trials, our employees, our business partners and our other stakeholders. Accordingly, our cybersecurity program is designed to identify, assess, manage and mitigate material risks from cybersecurity threats through a variety of measures, including risk assessments, implementation of security measures, and ongoing monitoring of systems and networks. In collaboration with our third-party IT service providers, a cross-functional team comprised of representatives from our administrative, finance and legal functions actively monitor the current threat landscape in an effort to identify material risks arising from new and evolving cybersecurity threats. We also engage external experts, including IT experts, other consultants, and auditors to evaluate our cybersecurity measures and risk management processes.

We also identify our cybersecurity threat risks by comparing our processes to industry standards and best practices as well as by engaging experts to manage our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, the activities we undertake include the following:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws, including industry-specific laws such as HIPAA, as applicable;
- through our policies, practices and contracts (as applicable), employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, which are evaluated and improved through vulnerability assessments and other evaluations on a routine basis;
- provide training for our employees regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- leverage threat intelligence available to us and our third-party IT service provider to help us identify, protect, detect, respond and recover if there is an actual or potential cybersecurity incident; and
- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Board Oversight of Cybersecurity Risk Management and Governance

Our Board is responsible for general oversight of our risk environment and associated management policies and practices and has delegated to our Audit Committee the responsibility for oversight of certain major risk categories and exposures, including with respect to cybersecurity and management processes to monitor and control them. The Audit Committee meets regularly throughout the year and, on no less than a quarterly basis, receives and reviews a report from management, including our Chief Financial Officer and General Counsel, regarding our IT, cybersecurity, data security, and physical security risk, including any suspected material or immaterial cybersecurity incidents during the preceding quarter, if any, and discusses such matters with appropriate management and other personnel. In addition, on a semi-annual basis, the Audit Committee receives a report from our primary third-party IT and cybersecurity provider regarding our IT environment, overall cybersecurity risk management program and strategy and education regarding emerging trends and threats.

Management's Role in Cybersecurity Risk Management and Governance

Our executive management team is responsible for assessing and managing material risks from cybersecurity threats and possess relevant experience and expertise in various disciplines that are key to effectively managing such risks. The experience and expertise of our executive management team is also supplemented by our external IT service providers that collectively have extensive, broad experience and expertise in these areas. Our executive management team reports information about such risks to the Audit Committee of the Board on at least a quarterly basis.

We depend on and engage various other third parties, including suppliers, vendors, and service providers, to support key elements of our business including our IT infrastructure. We have implemented various control processes designed to address cybersecurity threat risks associated with our use of such third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence. Our management is informed about and monitors the prevention, detection, mitigation, and remediation of cybersecurity incidents, including through the receipt of notifications from service providers and reliance on communications with risk management, legal, IT, and/or compliance personnel. In addition, cybersecurity risks and posture are, as appropriate and applicable, a factor considered in the selection process prior to our engagement of third-party service providers.

In response to an identified cybersecurity incident, a group comprised of appropriate management personnel, our third-party IT service providers and, depending on the scope and severity of the incident, additional third-party subject matters experts, will be assembled to develop and implement a response strategy to contain, control, and remediate the cybersecurity incident, including securing our affected systems and/or information, mitigating harmful effects of the incident, preventing further compromises, and communicating information to affected parties, regulatory agencies and law enforcement, as necessary. This group will also report any such cybersecurity incident to the Audit Committee of the Board.

Assessment of Cybersecurity Risk

The potential impact of risks from cybersecurity threats are assessed on an ongoing basis by both management and the Board, including how such risks could materially affect our business strategy, operational results, and financial condition, and from time-to-time we engage third-parties to provide independent risk assessments.

As of the date of this Annual Report, we have not experienced a cybersecurity incident that results in a material effect on our business strategy, results of operations or financial condition, but we cannot provide assurance that we will not be materially affected in the future by such an incident or risks related thereto.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading *Item 1A. Risk Factors – General Risks Related to Our Business and Operations*, which disclosures are incorporated by reference herein.

ITEM 2. PROPERTIES

We currently have a short-term lease for office space in Boston, Massachusetts which we use for our corporate offices. In addition, we previously had a short-term agreement to utilize membership-based co-working space in Charlottesville, Virginia, which was terminated in the first quarter of 2024. Rent expense related to our short-term agreements was approximately $57,112 and $34,692 for the years ended December 31, 2025 and 2024, respectively.

We believe the space is adequate to meet our near-term needs.

ITEM 3. LEGAL PROCEEDINGS

The information in *Note 8, Commitments and Contingencies — Legal Proceedings* to our consolidated financial statements included in, *Part II — Item 8 — Financial Statements and Supplementary Data* of this Annual Report is incorporated herein by reference.

In addition, from time to time, we are subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business, which may include employment matters, breach of contract disputes and stockholder litigation. Such actions and proceedings are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. We record a liability in our consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, when we have assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, we record the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. We disclose a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that a material loss may have been incurred. In the opinion of management, as of the date hereof, the amount of liability, if any, with respect to these matters, individually or in the aggregate, will not materially affect our consolidated results of operations, financial position or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades publicly on the Nasdaq Capital Market under the symbol "CRVO."

Holders

As of March 11, 2026, there were 102 record holders of our common stock. This does not include beneficial owners of our common stock whose stock is held in nominee or "street name".

Dividends

To date, we have not declared or paid any cash dividends on our common stock and do not intend to do so in the near future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information set forth in, *Part III — Item 12 (Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters)* of this Annual Report is incorporated herein by reference to the extent required by Item 201(d) of Regulation S-K.

Recent Unregistered Sales of Equity Securities and Use of Proceeds

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Overview

We are a clinical-stage biotechnology company developing treatments for age-related brain disorders. Our lead drug candidate, neflamapimod, is an investigational, orally administered small-molecule drug that readily crosses the blood–brain barrier and selectively inhibits the enzyme p38α, a key driver of neuroinflammation and synaptic dysfunction. By targeting the critical disease processes underlying degenerative disorders of the brain, neflamapimod has the potential to reverse synaptic dysfunction, improve neuron health, and slow or prevent disease progression. Neflamapimod is currently in clinical development for the treatment of DLB, our lead indication, as well as nfvPPA, RAS, and ALS.

Our novel approach focuses on reducing the impact of neuroinflammation, which we believe is a key factor in the manifestation of degenerative diseases of the brain. Chronic activation of p38α in the brains of people with certain neurodegenerative diseases is believed to impair how neurons communicate through synapses. This synaptic dysfunction leads to deterioration of cognitive and motor abilities. Left untreated, synaptic dysfunction can result in irreversible 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 many major neurodegenerative disorders,

including DLB, initially involves a protracted period of reversible functional loss, particularly with respect to the synapses. We believe that inhibiting p38α activity in the brain has the potential to reverse the clinical progression observed in the early-stages of certain neurodegenerative diseases, as well as slow further progression by delaying permanent synaptic dysfunction and neuron death, by interfering with key pathogenic drivers of disease.

We believe we are a leader in the industry in developing a treatment for DLB, a disease with no approved therapies in the US or European Union despite being the second most common progressive dementia. Neflamapimod is the only clinical drug candidate that, to our knowledge, has shown statistically significant improvements on clinical endpoints and a biomarker of neurodegeneration in both a Phase 2a and Phase 2b clinical trial. Differentiating our approach from potential competitors, we believe we are also the only company specifically targeting the treatment of DLB patients without AD co-pathology. While DLB patients with AD co-pathology generally have significant, irreversible neuronal loss, DLB without AD co-pathology is primarily a disease of functional deficits of synapses that we believe is more treatable. We believe if neflamapimod is given in the early stages of certain degenerative diseases of the brain like DLB without AD co-pathology, it may reverse synaptic dysfunction, improve neuron health and function, and slow further progression by delaying synaptic dysfunction and neuronal death. We believe this approach enhances the alignment of our development path with neflamapimod's mechanism of action, reduces the heterogeneity of our target patient population, and provides the opportunity to demonstrate heightened clinical effect in shorter duration trials.

Financial Summary

As of December 31, 2025, we had cash, cash equivalents and marketable securities of approximately $20.9 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, 2025, was $97.7 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 losses were $27.0 million and $16.3 million in the years ended December 31, 2025 and 2024, respectively. We expect our expenses will increase in connection with our ongoing activities, as we:

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

Based on our current operating plan, we do not believe our existing cash, cash equivalents and marketable securities on hand as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance of the consolidated financial statements included in this Annual Report. The consolidated financial statements appearing elsewhere in this Annual Report have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business and do not include any adjustments that might result from the outcome of this uncertainty.

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 and, in August 2024, we were awarded an additional $0.3 million under our NIA Grant. Funding from the NIA Grant was to be received in three annual installments and recognized as grant revenue as the qualifying expenses related thereto are incurred. During the year ended December 31, 2025, $4.0 million of grant funding was recognized as revenue, of which $3.6 million had been received and the remaining $0.4 million was recorded as grant receivable. During the year ended December 31, 2024, $9.7 million of grant funding was recognized as revenue, of which $7.5 million had been received and the remaining $2.3 million was recorded as grant receivable. In January 2026, we were informed that we will not receive the final 2% of year 3 grant funding that remained unavailable as of December 31, 2025, or approximately $0.1 million, as a result of agency-wide reductions in NIA funding.

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, nonclinical testing organizations, consultants, and other third-party vendors, collaborators and service providers;
- costs related to production of clinical materials, including fees paid to CDMOs;
- vendor expenses related to the execution of nonclinical 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. Personnel and other operating expenses incurred for our research and development programs primarily relate to salaries and benefits, stock-based compensation, and facility expenses.

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

Interest Income

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

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations:

	Year Ended December 31,			
	2025	**2024**	**$ Change**	**% Change**
Grant revenue	$ 4,006,510	$ 9,737,974	$ (5,731,464)	(59)%
Operating expenses:				
Research and development	21,817,072	18,798,343	3,018,729	16%
General and administrative	10,484,315	9,166,762	1,317,553	14%
Total operating expenses	32,301,387	27,965,105	4,336,282	16%
Loss from operations	(28,294,877)	(18,227,131)	(10,067,746)	55%
Other income (expense):				
Other expense	(8,327)	(991)	(7,336)	(a)
Interest income	1,336,837	1,937,427	(600,590)	(31)%
Total other income	1,328,510	1,936,436	(607,926)	(31)%
Net loss	$(26,966,367)	$(16,290,695)	$(10,675,672)	66%

*(a) Not meaningful

Grant Revenue

Grant revenue was $4.0 million and $9.7 million for the years ended December 31, 2025 and 2024, respectively. In each year, all grant revenue is related to the NIA Grant which funded our RewinD-LB Trial. The year-over-year decrease of $5.7 million is due to the completion of the Randomized Phase of the RewinD-LB Trial in late 2024, followed by the subsequent completion of the Extension Phase in mid-2025.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2025 and 2024:

	Years Ended December 31,			
	2025	2024	$ Change	% Change
Dementia with Lewy bodies	$ 7,052,512	$12,102,842	$(5,050,330)	(42)%
Frontotemporal disorders (incl. nfvPPA)	1,217,784	36,853	1,180,931	(a)
Recovery after stroke	1,427,966	391,659	1,036,307	265%
Other clinical* and nonclinical	2,504,863	2,499,202	5,661	—%
Personnel costs, excluding stock-based compensation	5,745,558	2,187,221	3,558,337	163%
Stock-based compensation	482,669	218,822	263,847	121%
Other research and development expenses, including CMC	3,385,720	1,361,744	2,023,976	149%
Total research and development expenses	$21,817,072	$18,798,343	$ 3,018,729	16%

* Includes early-stage clinical studies that are not indication-specific and related costs.
(a) Not meaningful.

Research and development expenses were $21.8 million for the year ended December 31, 2025, compared to $18.8 million for the year ended December 31, 2024. The increase of $3.0 million was due to several factors. The increase of personnel costs of $3.6 million and increase in stock-based compensation of $0.3 million were driven by higher headcount and an increase in outsourced consulting costs. The increase of $2.0 million in costs related to CMC activities and other research and development expenses is primarily related to the analysis of the batch issues identified during the Randomized Phase of the RewinD-LB Trial and the implementation of our planned pre-Phase 3 manufacturing improvements. Finally, we saw an aggregate increase of $2.2 million related to non-DLB clinical work for neflamapimod, including costs related to our RESTORE Trial in RAS and Phase 2a trial in nfvPPA, which were both initiated during 2025. These amounts were offset by a decrease of $5.1 million in DLB-related clinical spend due to the completion of the Randomized Phase of the RewinD-LB Trial in December 2024, followed by the subsequent completion of the Extension Phase in mid-2025.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by functional area for the years ended December 31, 2025 and 2024:

	Years Ended December 31,			
	2025	2024	$ Change	% Change
Personnel costs, excluding stock-based compensation	$ 4,988,705	$ 3,995,114	$ 993,591	25%
Stock-based compensation	965,965	1,186,900	(220,935)	(19)%
Professional fees	2,752,710	2,684,386	68,324	3%
Insurance, taxes and similar fees	1,166,374	985,481	180,893	18%
Other general and administrative expenses, including IT, facilities, supplies and similar costs	610,561	314,879	295,682	94%
Total general and administrative expenses	$10,484,315	$ 9,166,760	$ 1,317,555	14%

General and administrative expenses were $10.5 million for the year ended December 31, 2025, compared to $9.2 million for the year ended December 31, 2024. The increase of $1.3 million was primarily due to the increase of $1.0 million in personnel costs, the increase of $0.3 million in other general and administrative expenses, the increase of $0.2 million in insurance and taxes, and the increase of $0.1 million in professional fees, partially offset by a decrease of $0.2 million in stock-based compensation. The increase in personnel costs was primarily driven by headcount and additional severance costs. The decrease in stock-based compensation was primarily due to higher stock compensation expense related to stock option modifications in the prior year in comparison to current year.

Other Expense

There was a *de minimis* amount of other expense for the years ended December 31, 2025 and 2024.

Interest Income

Interest income was $1.3 million and $1.9 million for the years ended December 31, 2025 and 2024, respectively. The decrease was primarily due to lower investment balances as cash was used for operations.

Liquidity and Capital Resources

Capital Requirements

From the date of our inception through December 31, 2025, our operations have primarily been financed through the issuance of common stock, convertible preferred stock and convertible debt financings. As of December 31, 2025, we had approximately $20.9 million of cash, cash equivalents and marketable securities. We have not generated positive cash flows from operations and as of December 31, 2025, we had an accumulated deficit of approximately $97.7 million. In January 2023, we were awarded a $21.0 million grant from the NIA to support the RewinD-LB Trial, which was received over a three-year period. In August 2024, we received an additional $0.3 million from the NIA. As of December 31, 2025, total cash funding of $20.5 million had been received from the NIA Grant and approximately $0.6 million in funding is remaining. In March 2025, we received access to 90% of the year 3 funding and, in June 2025, we received access to an additional 8% of the year 3 funding provided for in the NIA Grant, due to then-current NIA policy as a result of the US government currently being funded on the basis of a continuing resolution. Accordingly, as of December 31, 2025, we determined that the receipt of the remaining 2% of funding was not probable and we would not account for the remaining 2% of funding unless and until received. In January 2026, we were informed that we will not receive the final 2% of year 3 grant funding that remained unavailable as of December 31, 2025, or approximately $0.1 million, as a result of agency-wide reductions in NIA funding.

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

On May 21, 2025, we entered into the Sales Agreement with Leerink Partners, LLC, as sales agent, pursuant to which we may offer and sell shares of common stock from time-to-time with an aggregate offering price of up to $50.0 million under an “at-the-market" offering program. During the year ended December 31, 2025, we sold 550,000 shares of common stock to an institutional investor in a block sale for proceeds of $4.7 million, net of $0.1 million of issuance costs.

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.

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

Based on our current operating plan, we do not believe our existing cash, cash equivalents and marketable securities on hand as of December 31, 2025, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance of the consolidated financial statements included in this Annual Report. Accordingly, substantial doubt exists about our ability to continue as a going concern within one year after the date the consolidated financial statements included elsewhere in this Annual Report are issued. 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, royalty arrangements, or other dilutive or non-dilutive capital sources, including potential collaborations, licenses

and/or other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through a debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we may need to delay, reduce or terminate planned activities to reduce costs, including our development or commercialization activities for neflamapimod. We might also be required to seek funds through arrangements with third parties that require us to relinquish certain of our rights to neflamapimod or otherwise agree to terms unfavorable to us.

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

- the enrollment, progress, timing, costs and results of our clinical trials and other development activities for neflamapimod;
- 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

	Year Ended December 31,	
	2025	**2024**
Net cash used in operating activities	$ (23,449,963)	$ (16,530,827)
Net cash provided by (used in) investing activities	18,097,249	(28,661,129)
Net cash provided by financing activities	4,588,687	46,398,606
Net (decrease) increase in cash and cash equivalents	$ (764,027)	$ 1,206,650

Operating Activities

For the year ended December 31, 2025, cash used in operating activities was $23.4 million. The net cash outflow from operations primarily resulted from net loss of $27.0 million and accretion of discount on marketable securities of $0.9 million, offset by changes in operating assets and liabilities of $2.9 million and $1.4 million for stock-based compensation.

For the year ended December 31, 2024, cash used in operating activities was $16.5 million. The net cash outflow from operations primarily resulted from net loss of $16.3 million, accretion of discount on marketable securities of $1.2 million and changes in operating assets and liabilities of $0.4 million, partially offset by a non-cash expense of $1.4 million for stock-based compensation.

Investing Activities

For the year ended December 31, 2025, cash provided by investing activities was $18.1 million due to the maturities of marketable securities, partially offset by the purchases of marketable securities.

For the year ended December 31, 2024, cash used in investing activities was $28.7 million due to the purchase of marketable securities, partially offset by the maturities of marketable securities.

Financing Activities

For the year ended December 31, 2025, net cash provided by financing activities was $4.6 million due to proceeds from the sale of common stock for $4.6 million, net of offering costs, pursuant to the Sales Agreement.

For the year ended December 31, 2024, net cash provided by financing activities was $46.4 million due to proceeds from the sale of common stock and the Pre-Funded Warrants for gross proceeds of approximately $50.0 million, partially offset by the payment of issuance costs related to the sale of common stock and the Pre-Funded Warrants of $3.6 million, in each case, in connection with the 2024 Private Placement.

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 US GAAP. 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.

Research and Development Costs

We believe research and development costs is a critical accounting policy and estimate. 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 an estimate of expense for nonclinical studies and clinical trials in the period the expense is incurred. Estimates are based on the services performed pursuant to contracts with research institutions, CROs in connection with clinical studies, investigative sites in connection with clinical studies, vendors in connection with nonclinical development activities, and CMOs in connection with the production of materials for clinical trials. Further, we record 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 expense 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 consolidated 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 nonclinical studies and clinical trial expenses.

Stock-based Compensation

We believe stock-based compensation is one of our more significant accounting policies used in the preparation of our consolidated financial statements. 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 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 August 2023. 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 US Treasury yield curve in effect at the date of grant for zero-coupon US 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.

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 in, "*Part II — Item 8 — Financial Statements*" of this Annual Report is incorporated herein by reference.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

As a "smaller reporting company" (as such term is defined in Rule 12b-2 of the Exchange Act), we are not required to provide the information described in Item 305 of Regulation S-K and, accordingly, the information required by Item 7A of Form 10-K has been omitted from this Annual Report.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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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, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity 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, 2025 and 2024, 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 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 matters communicated below are matters arising from the current period audit of the financial statements that were 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Research and Development Expenses Related to Nonclinical Studies and Clinical Trials
As discussed in Note 3 to the financial statements, the Company estimates the amount of nonclicinal study and clinical trial expenses incurred in each period. Estimates are based on the services performed by research institutions, contract research organizations, investigative sites, vendors in connection with clinical activities, and contract manufacturing organizations. Further, the Company records expenses related to clinical trials based on the level of subject enrollment and activity according to the related agreement and makes judgments and estimates in determining the amount of research and development expense and related accrued or prepaid 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 may be reflected in the consolidated financial statements as an accrued or prepaid expense. Research and development expenses related to clinical trials, as described above, are included within the $21.8 million of research and development expenses recorded on the Company's statement of operations and comprehensive loss. The Company's accrual for clinical development costs totaled $1.5 million at December 31, 2025, as disclosed in Note 7 and prepayment for clinical expenses totaled $0.7 million at December 31, 2025, as disclosed in Note 6.

We identified the research and development expenses related to nonclinical studies and clinical trials to be a critical audit matter because auditing the Company's expenses is complex as the information necessary to make an estimate is accumulated from multiple sources and there may be delays in invoicing from clinical study sites and other vendors, or payments may depend on factors such as the completion of clinical trial milestones. Additionally, in certain circumstances, it requires judgment, as the timing and pattern of vendor invoicing may not correspond to the level of services provided.

Our audit procedures to test the research and development expenses related to nonclinical studies and clinical trials included, among others:

- We inspected contracts and purchase orders with certain third parties and agreed key milestones, activities, timing, and costs to management's schedules.
- We tested the completeness and accuracy of the underlying data used by management to estimate the service performed and associated costs incurred to date.
- We corroborated the progress of a sample of research and development activities through inquiries with the Company's research and development personnel and sent confirmations directly to certain third-party vendors.
- We tested a sample of invoices received from third parties and cash disbursements before and after year-end to assess completeness of accrued expenses or the existence of prepaid expenses.

/s/ RSM US LLP

We have served as the Company's auditor since 2017.

Boston, Massachusetts
March 13, 2026

CervoMed Inc.
Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 8,235,469	$ 8,999,496
Marketable securities	12,628,970	29,922,523
Prepaid expenses and other current assets	1,267,005	1,905,360
Deferred offering costs	320,581	—
Grant receivable	426,993	2,254,231
Total current assets	22,879,018	43,081,610
Total assets	$ 22,879,018	$ 43,081,610
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,454,118	$ 1,511,440
Accrued expenses and other current liabilities	3,201,999	2,367,842
Total current liabilities	4,656,117	3,879,282
Total liabilities	4,656,117	3,879,282
Commitments and Contingencies (Note 8)		
Stockholders' Equity:		
Series A preferred stock $0.001 par value: 30,000,000 authorized at December 31, 2025 and 2024, 0 shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.001 par value: 1,000,000,000 shares authorized at December 31, 2025 and 2024: 9,252,719 and 8,702,719 shares issued and outstanding at December 31, 2025 and 2024, respectively	9,252	8,702
Additional paid-in capital	115,905,684	109,868,913
Accumulated other comprehensive income	5,816	56,197
Accumulated deficit	(97,697,851)	(70,731,484)
Total stockholders' equity	18,222,901	39,202,328
Total liabilities and stockholders' equity	$ 22,879,018	$ 43,081,610

See accompanying notes to consolidated financial statements

CervoMed Inc.
Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2025	**2024**
Grant revenue	$ 4,006,510	$ 9,737,974
Operating expenses:		
Research and development	21,817,072	18,798,343
General and administrative	10,484,315	9,166,762
Total operating expenses	32,301,387	27,965,105
Loss from operations	(28,294,877)	(18,227,131)
Other income (expense):		
Other expense	(8,327)	(991)
Interest income	1,336,837	1,937,427
Total other income, net	1,328,510	1,936,436
Net loss	$ (26,966,367)	$ (16,290,695)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (2.98)	$ (2.02)
Weighted average shares outstanding, basic and diluted	9,041,760	8,073,155
Net loss:		
Net unrealized (loss) gain on marketable securities	(50,381)	56,197
Total comprehensive loss	$ (27,016,748)	$ (16,234,498)

See accompanying notes to consolidated financial statements

CervoMed Inc.
Consolidated Statements of Stockholders' Equity

	Years Ended December 31, 2025 and 2024					
	Common Stock		Additional Paid-in	Accumulated other comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	income	Deficit	Equity
Balance at December 31, 2023	5,674,520	$ 5,674	$ 61,811,889	$ —	$ (54,440,789)	$ 7,376,774
Issuance of common stock, prefunded warrants and common stock warrants, net of offering costs	2,083,262	2,083	46,396,523	—	—	46,398,606
Stock options granted in lieu of compensation	—	—	255,724	—	—	255,724
Cashless exercise of prefunded warrants	944,937	945	(945)	—	—	—
Stock-based compensation expense	—	—	1,405,722	—	—	1,405,722
Unrealized gain on marketable securities	—	—	—	56,197	—	56,197
Net loss	—	—	—	—	(16,290,695)	(16,290,695)
Balance at December 31, 2024	8,702,719	$ 8,702	$109,868,913	$ 56,197	$ (70,731,484)	$ 39,202,328
Sale of common stock, net of issuance costs	550,000	550	4,588,137	—	—	4,588,687
Stock-based compensation expense	—	—	1,448,634	—	—	1,448,634
Unrealized loss on marketable securities	—	—	—	(50,381)	—	(50,381)
Net loss	—	—	—	—	(26,966,367)	(26,966,367)
Balance at December 31, 2025	9,252,719	$ 9,252	$115,905,684	$ 5,816	$ (97,697,851)	$ 18,222,901

See accompanying notes to consolidated financial statements

CervoMed Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (26,966,367)	$ (16,290,695)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on marketable securities, net	(854,077)	(1,205,197)
Stock-based compensation expense	1,448,634	1,405,722
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	638,355	(641,089)
Deferred offering costs	(310,581)	—
Accounts payable	(67,322)	848,969
Accrued expenses and other liabilities	834,157	690,290
Grant receivable	1,827,238	(1,338,827)
Net cash used in operating activities	(23,449,963)	(16,530,827)
Cash flows from investing activities:		
Purchase of marketable securities	(25,402,751)	(48,101,129)
Maturities of marketable securities	43,500,000	19,440,000
Net cash provided by (used in) investing activities	18,097,249	(28,661,129)
Cash flows from financing activities:		
Proceeds from sale of common stock, prefunded warrants and common stock warrants	—	46,398,606
Sale of common stock under At-the-Market Sales Agreement, net of issuance costs	4,588,687	—
Net cash provided by financing activities	4,588,687	46,398,606
Net (decrease) increase in cash and cash equivalents	(764,027)	1,206,650
Cash and cash equivalents at beginning of the year	8,999,496	7,792,846
Cash and cash equivalents at end of the year	$ 8,235,469	$ 8,999,496
Supplemental disclosure of non-cash investing and financing activities:		
Stock options granted in lieu of cash bonus	$ —	$ 255,724
Cashless exercise of pre-funded warrants	$ —	$ 945
Deferred offering costs in accounts payable	$ 10,000	$ —

See accompanying notes to consolidated financial statements

Note 1. The Company and Description of Business

The Company is a corporation organized under the laws of the state of Delaware and headquartered in Boston, Massachusetts. The Company is a clinical-stage biotechnology company developing treatments for age-related brain disorders. Its lead drug candidate, neflamapimod, is an oral, small molecule targeting critical disease processes underlying degenerative disorders of the brain by inhibiting a key enzyme involved in neuroinflammation and neurodegeneration. The Company recently completed its RewinD-LB Trial, a Phase 2b study of neflamapimod in patients with DLB funded primarily by a $21.3 million grant from the NIA.

Note 2. Liquidity and Capital Resources

Liquidity and Capital Resources

The Company has $20.9 million of cash, cash equivalents, and marketable securities as of December 31, 2025, has generated negative cash flows from operations and had an accumulated deficit of $97.7 million as of December 31, 2025. 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 its current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. The Company intends to continue to seek funds through equity offerings, debt financings or other capital sources, including grants, potential collaborations, licenses and other similar arrangements. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms, or at all. If the Company does raise additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect the Company's stockholders' rights. If the Company raises additional capital through a debt financing, it may be subject to covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on the Company's financial condition and on its ability to pursue its business plans and strategies. If the Company is unable to raise sufficient capital when needed, it may need to delay, reduce or terminate planned activities to reduce costs, including development or commercialization activities for neflamapimod. The Company might also be required to seek funds through arrangements with third parties that require it to relinquish certain of its rights to neflamapimod or otherwise agree to terms unfavorable to the Company.

Accordingly, substantial doubt about the Company's ability to continue as a going concern is not alleviated. Based on its current operating plan, the Company does not believe its existing cash, cash equivalents and marketable securities on hand of $20.9 million as of December 31, 2025 will enable the Company to fund its operating expenses and capital expenditure requirements for at least twelve months from the issuance of these consolidated financial statements.

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 the uncertainty described in this Note 2.

Risks and Uncertainties

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

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

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, 2025 and 2024.

Marketable Securities

The Company classifies its marketable securities as available-for-sale, which include commercial paper, US government debt securities, and corporate debt securities with original maturities of greater than 90 days from date of purchase. These securities are carried at fair value, with unrealized gains and losses reported on the consolidated statements of operations and comprehensive loss and accumulated other comprehensive income within stockholders' equity until realized. Purchase discounts are accreted using the effective interest method over the term of the related security and such accretion is included in interest income on the accompanying consolidated statements of operations and comprehensive loss.

The Company evaluates its investments in marketable securities for impairment at each reporting period when the fair value is below amortized cost. If the Company intends to sell the security, or it is more likely than not the Company will be required to sell the security before recovery of amortized cost, the entire impairment is included in earnings. The Company did not record any impairment on marketable securities during years ended December 31, 2025 and 2024. There was no allowance for credit losses as of December 31, 2025 or December 31, 2024.

Equity Issuance Costs

The Company capitalizes costs directly associated with equity financings as deferred offering costs on its consolidated balance sheet. These costs remain capitalized until such financings are consummated, at which time such costs are recorded against the gross proceeds from the applicable financing. With respect to financings conducted on an ongoing basis, such as at-the-market offerings, costs are recognized ratably as funds are received in proportion to the aggregate offering amount. If a financing is abandoned, any remaining deferred offering costs are expensed.

As of December 31, 2025, there were $0.3 million of deferred offering costs related to the Sales Agreement. There were no deferred offering costs as of December 31, 2024, as the Sales Agreement was entered into in May 2025.

Fair Value of Financial Instruments

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

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

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

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

Leases

The Company accounts for leases in accordance with ASC Topic 842, Leases, which requires a lessee to recognize an ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and expense recognition in the statement of operations and comprehensive loss as well as the reduction of the ROU asset. The standard provides a number of optional practical expedients in transition. The Company has elected to apply (i) the practical expedient, which allows us to not separate lease and non-lease components, for new leases and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes 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 are 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 an estimate of expense for nonclinical studies and clinical trials in the period the expense is incurred. Estimates are based on the services performed pursuant to contracts with research institutions, CROs in connection with clinical studies, investigative sites in connection with clinical studies, vendors in connection with nonclinical development activities, and CMOs in connection with the production of materials for clinical trials. Further, the Company records 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 expense 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 consolidated financial statements as prepaid or accrued research and development.

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

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 and comprehensive loss.

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 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 term is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the Company stock options, taking into consideration multiple vesting tranches. The Company utilizes this method due to lack of historical data and the plain-vanilla nature of the Company's stock-based awards.

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

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

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

Grant Revenue

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

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

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 the statements of operations and comprehensive loss for the period that includes the enactment date.

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

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

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

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. Diluted net 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 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,	
	2025	**2024**
Common stock warrants	2,598,337	2,609,289
Stock options	992,701	636,802
	3,591,038	3,246,091

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): "Improvements to Income Tax Disclosures" ("ASU 2023-09"). ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements as well. The guidance in ASU 2023-09 is effective for annual reporting periods in fiscal years beginning after December 15, 2024 and was adopted prospectively by the Company during the year ended December 31, 2025. The adoption of ASU 2023-09 impacted the Company's income tax disclosures only and did not have an impact on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, "Disaggregation of Income Statement Expenses" ("ASU 2024-03"). ASU 2024-03 requires additional disclosure of specific types of expenses included in the expense captions presented on the face of the statement of operations and comprehensive loss, as well as disclosures about selling expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its consolidated financial statements and disclosures.

Note 4. Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, cash equivalents, marketable securities, and accounts payable. The Company's cash, cash equivalents, and accounts payable approximate fair value due to their relatively short maturities.

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

	December 31, 2025		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents:			
Money market accounts	$ 6,300,291	$ —	$ —
Commercial paper	—	999,330	—
Marketable securities:			
Commercial paper	—	11,139,880	—
US treasury bonds	—	1,238,538	—
US government agency bonds	—	250,552	—
Total assets measured at fair value	$ 6,300,291	$ 13,628,300	$ —

	December 31, 2024		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents (money market accounts)	$ 7,559,336	$ —	$ —
Marketable securities:			
Commercial paper	—	18,032,943	—
US treasury bonds	—	7,951,060	—
US government agency bonds	—	3,938,520	—
Total assets measured at fair value	$ 7,559,336	$ 29,922,523	$ —

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

The following is a summary of the Company's marketable securities which provides a reconciliation of amortized cost basis to fair value including cumulative unrealized gains and losses as of December 31, 2025 and 2024:

	December 31, 2025			
	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Commercial paper	$11,134,856	$ 5,024	$ —	$11,139,880
US treasury bonds	1,237,794	744	—	1,238,538
US government agency bonds	250,504	48	—	250,552
Total	$12,623,154	$ 5,816	$ —	$12,628,970

	December 31, 2024			
	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Commercial paper	$18,019,334	$ 16,393	$ (2,784)	$18,032,943
US treasury bonds	7,920,620	30,440	—	7,951,060
US government agency bonds	3,926,372	12,148	—	3,938,520
Total	$29,866,326	$ 58,981	$ (2,784)	$29,922,523

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2025 and 2024.

Note 5. Significant Agreements and Contracts

Vertex Option and License Agreement

In August 2012, the Company entered the Vertex Agreement 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 AD and related CNS 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 US, or a similar filing for a non-US 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, 2025 and 2024.

National Institute of Aging Grant

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

The total revenue recognized from the NIA Grant was $4.0 million and $9.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, aggregate total cash funding of $20.5 million has been received from the NIA Grant, resulting in approximately $0.6 million in funding remaining. The Company has recorded $0.4 million as a receivable in the consolidated balance sheet at December 31, 2025, for allowable expenses incurred prior to December 31, 2025, which is expected to be received subsequent to December 31, 2025. As of December 31, 2024, $2.3 million was recorded as a receivable in the consolidated balance sheet, for allowable expenses incurred during the year ended December 31, 2024.

In March 2025, the Company received access to 90% of the year 3 funding and, in June 2025, the Company received access to an additional 8% of the year 3 funding provided for in the NIA Grant, due to then-current NIA policy as a result of the US government currently being funded on the basis of a continuing resolution. Accordingly, as of December 31, 2025, we determined that the receipt of the remaining 2% of funding is not probable and we would not account for the remaining 2% of funding unless and until received. In January 2026, we were informed that we will not receive the final 2% of year 3 grant funding that remained unavailable as of December 31, 2025, or approximately $0.1 million, as a result of agency-wide reductions in NIA funding.

Note 6. Prepaid Expenses

Prepaid expenses consisted of the following:

	December 31, 2025	December 31, 2024
Clinical expenses	$ 677,604	$ 1,149,343
Insurance	405,795	443,141
Professional services	119,803	95,218
Dues and memberships	43,828	11,777
Other	19,975	205,881
Total	$ 1,267,005	$ 1,905,360

Note 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2025	December 31, 2024
Employee compensation costs	$ 1,061,766	$ 803,193
Clinical development costs	1,484,318	1,158,783
Professional fees	532,076	249,527
State franchise and excise tax	40,456	40,456
Other	83,383	115,883
Total	$ 3,201,999	$ 2,367,842

Note 8. Commitments and Contingencies

Operating Leases

The Company has a short-term lease for office space in Boston, Massachusetts. Lease expense was approximately $57,112 and $34,692 for the years ended December 31, 2025 and 2024, respectively.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities and CROs to assist in the performance of research and development activities and with CDMOs to assist with CMC-related activities. Expenditures to CROs and other CDMOs represent a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Defined Contribution Retirement Plan

The Company has established its 401(k) Plan, which covers all employees who qualify under the terms of the plan. Eligible employees may elect to contribute to the 401(k) Plan up to 90% of their compensation, limited by the IRS-imposed maximum. The Company provides a safe harbor match with a maximum amount of 4% of the participant's compensation. There were total contributions under the 401(k) Plan of $0.4 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively.

Legal Proceedings

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, the former Chief Executive Officer of the Company's legal predecessor, under the caption Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys' fees and costs. On December 30, 2014, the Company filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to the Company's petition to compel arbitration and a motion to stay the action. After a related hearing on April 14, 2015, the court granted the Company's petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. On November 19, 2018 at an Order to Show Cause Re Dismissal Hearing, the court found sufficient grounds not to dismiss the case and an arbitration hearing was scheduled, originally for November 2020 but later postponed due to the COVID-19 pandemic and related restrictions on gatherings in the State of California. In addition, following the November 2018 hearing, an automatic stay was placed on the arbitration in connection with the plaintiff filing for personal bankruptcy protection. On October 22, 2021, following a determination by the bankruptcy trustee not to pursue the claims and release them back to the plaintiff, the parties entered into a stipulation to abandon arbitration and return the matter to state court. A case management conference was held on February 23, 2022 at which an initial trial date of May 24, 2023 was set, and the parties have agreed to stipulate to mediation in advance of the trial. On October 20, 2022, the parties filed a joint stipulation to continue the trial and certain deadlines related to the mediation in order to allow plaintiff's counsel to continue to seek treatment for an ongoing medical issue. On November 1, 2022, based on the parties' joint stipulation, the court entered an order continuing the trial date to October 25, 2023, on October 6, 2023, the court entered an order further continuing the trial date to April 24, 2024, and on March 3, 2024, based on an additional joint stipulation of the parties, the court entered an order continuing the trial date to October 23, 2024. On September 4, 2024, due to certain delays in discovery as a result of, among other things, plaintiff's counsel's health complications, the parties filed a joint stipulation to continue the trial and certain deadlines related thereto. On October 9, 2024, based on the parties' joint stipulation, the court entered an order continuing the trial date to April 30, 2025. On January 6, 2025, the Company filed a Motion for Summary Adjudication against plaintiff's claims for promissory fraud, negligent misrepresentation, and common counts. On February 21, 2025, the parties filed a joint stipulation to continue the trial and certain deadlines related thereto and, on March 12, 2025, the court entered an order continuing the trial date to November 26, 2025. On October 22, 2025, pursuant to an additional joint stipulation to continue the trial and certain deadlines related thereto filed by the parties, the court entered an order continuing the trial date to May 13, 2026.

The Company is defending itself vigorously against the claims alleged in this matter. 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 adverse effect on the Company's financial position, results of operations and cash flows.

Note 9. Stockholders' Equity and Common Stock Warrants

April 2024 Private Placement

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

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

Warrants

As of December 31, 2025, the Company had the following warrants outstanding to acquire shares of its common stock:

	Outstanding	Range of exercise price per share	Expiration date
Historical Diffusion common stock warrants	22,434	$96.12	February 2026
Historical EIP common stock warrants	43,618	$19.81	April 2028
Series A common stock warrants	2,532,285	$39.24	April 2027
	2,598,337		

On February 11, 2026, the remaining historical Diffusion common stock warrants expired unexercised.

February 2024 Pre-Funded Warrant Exercise

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

December 2024 Pre-Funded Warrant Exercise

On December 11, 2024, 449,023 Pre-Funded Warrants to purchase common stock issued in connection with the closing of the 2024 Private Placement were exercised in full by the holder thereof pursuant to the cashless exercise provision of the Pre-Funded Warrants. Upon exercise, 45 shares were withheld in lieu of a cash payment of the exercise price and the holder was issued 448,978 shares of common stock.

May 2025 At-The-Market Offering

On May 12, 2025, the Company entered into the Sales Agreement with Leerink Partners LLC, as sales agent, pursuant to which the Company may offer and sell shares of common stock from time-to-time with an aggregate offering price of up to $50.0 million under an “at-the-market" offering program. During the year ended December 31, 2025, the Company sold 550,000 shares of common stock to an institutional investor in a block sale for proceeds of $4.7 million, net of $0.1 million of issuance costs.

Note 10. Stock-Based Compensation Stock

2015 Equity Plan

The 2015 Equity Plan provides for increases to the number of shares reserved for issuance thereunder each January 1 equal to 4.0% of the total shares of the Company’s common stock outstanding as of the immediately preceding December 31, unless a lesser amount is stipulated by the Compensation Committee of the Company’s Board. On January 1, 2025, the number of shares available for future issuance under the 2015 Equity Plan increased by 348,109. As of December 31, 2025, the term of the 2015 Equity Plan had expired and no additional shares will be issued thereunder.

2018 Employee, Director and Consultant Equity Incentive Plan

On March 28, 2018, EIP adopted the 2018 Plan, which was assumed by the Company pursuant to and in accordance with the terms of the Merger Agreement. Under the 2018 Plan, the Company may issue incentive stock options, non-qualified stock options, stock grants, and other stock-based awards to employees, directors, and consultants, as specified in the 2018 Plan and subject to applicable SEC and Nasdaq rules and regulations. The Board has the authority to determine to whom options or stock will be granted, the number of shares, the term, and the exercise price. Options granted under the 2018 Plan have a term of up to ten years and generally vest over a four-year period with 25% of the options vesting after one-year of service and the remainder vesting monthly thereafter. As of December 31, 2025, there were no shares available for issuance.

Inducement Grants

During the year ended December 31, 2024, the Company granted stock options to purchase an aggregate of 71,712 shares of common stock as material inducements to the employment of five new employees, in each case, in accordance with Nasdaq Listing Rule 5635(c)(4). Each such inducement option has a term of ten years and vests over a 36-month period commencing on the last day of the month in which the grant date occurred (subject to the employee's continued employment with the Company).

In June 2025, the Company granted a stock option to purchase an aggregate of 54,000 shares of common stock as material inducements to the employment of a new employee in accordance with Nasdaq Listing Rule 5635(c)(4). The inducement option has a term of ten years and vests over a 36-month period commencing on the last day of the month in which the grant date occurred (subject to the employee's continued employment with the Company).

In October 2025, the Company granted a stock option to purchase an aggregate of 75,000 shares of common stock as material inducements to the employment of a new employee in accordance with Nasdaq Listing Rule 5635(c)(4). The inducement option has a term of ten years and vests over a 36-month period commencing on the last day of the month in which the grant date occurred (subject to the employee's continued employment with the Company).

2025 Equity Plan

On April 14, 2025, the Board approved the 2025 Equity Plan, and the 2025 Equity Plan was subsequently approved by the Company's stockholders at its 2025 Annual Meeting of Stockholders on June 23, 2025. As of December 31, 2025, there were 735,200 shares available for future issuance under the 2025 Equity Plan.

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

	Year Ended December 31,	
	2025	2024
Research and development	$ 482,669	$ 218,822
General and administrative	965,965	1,186,900
Total stock-based compensation expense	$ 1,448,634	$ 1,405,722

The following table summarizes the activity related to all stock option grants for the year ended December 31, 2025:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Balance at January 1, 2025	636,802	$ 19.38	7.6	
Granted	466,600	$ 4.61		
Expired	(68,367)	$ 45.84		
Forfeited	(42,334)	$ 8.22		
Outstanding at December 31, 2025	992,701	$ 11.76	8.0	—
Exercisable at December 31, 2025	561,358	$ 15.92	7.2	—

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:

	Year Ended December 31,	
	2025	2024
Expected term (in years)	5.24- 5.76	5.25- 5.76
Risk-free interest rate	3.68- 4.35%	3.89- 4.46%
Expected volatility	71.55-76.68%	76.06-80.03%
Dividend yield	—	—

At December 31, 2025, there was $1.9 million of unrecognized compensation expense that will be recognized over a weighted-average period of 2.0 years.

During the year ended December 31, 2024, the Company granted 39,721 options in lieu of 2023 executive bonus compensation. No similar event occurred during the year ended December 31, 2025.

Effective May 31, 2024, the Company separated from its former Chief Financial Officer. Based on the terms of his separation agreement, unvested shares under previously granted option awards continued to vest on the schedule provided for in the applicable option award agreement through September 30, 2025. The Company accounted for the change in vesting terms as an improbable-to-probable modification of his stock options and recognized $0.3 million of expense in relation to this modification during the year ended December 31, 2024. In addition, the exercise period for any shares under previously granted option awards vested as of May 31, 2024 was extended to September 30, 2025. The Company accounted for the change in exercise terms as a probable-to-probable modification of his stock options and recognized $12,000 of expense in relation to this modification during the year ended December 31, 2024. As of October 1, 2025, all such option awards expired unexercised.

On April 14, 2025, the Board approved a separation agreement with the Company's former Chief Operating Officer, pursuant to which the executive's employment with the Company concluded effective July 1, 2025. Based on the terms of his separation agreement, unvested shares under previously granted option awards will continue to vest on the schedule provided for in the applicable option award agreement through September 30, 2026. The Company accounted for the change in vesting terms of his unvested stock options as an improbable-to-probable modification of his stock options and recognized $0.2 million of expense in relation to this modification during the year ended December 31, 2025. In addition, the exercise period for any shares under previously granted option awards vested as of April 14, 2025 was extended to September 30, 2026. The Company accounted for the change in exercise terms as probable-to-probable modification of his stock options and recognized $0.1 million of expense in relation to this modification during the year ended December 31, 2025.

Note 11. Income Taxes

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances the disclosures required for income taxes in the Company's annual consolidated financial statements. The guidance is effective for annual periods beginning after December 15, 2024. The Company adopted ASU 2023-09 prospectively, and the adoption impacted the Company's income tax disclosures only and did not have an impact on its consolidated financial statements.

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, 2025 and 2024:

	2025		2024	
	Total	%	Total	%
Rate reconciliation:				
Federal tax benefit at statutory rate	$ (5,671,648)	21.0%	$ (3,421,046)	21.0%
State tax, net of federal benefit	—	—%	(710,002)	4.4%
Research and development credits	(1,121,821)	4.2%	(526,015)	3.2%
Change in valuation allowance	6,188,171	(22.9)%	4,443,812	(27.3)%
Share-based compensation	—	—%	176,562	(1.1)%
Other	605,298	(2.3)%	36,689	(0.2)%
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, 2025 and 2024 consisted of the following:

	2025	2024
Deferred tax assets:		
Net operating loss	$ 21,388,936	$ 10,417,666
Research and development credits	2,367,496	1,228,255
Capitalized research expenditures	3,289,629	6,392,545
Stock-based compensation	977,321	698,886
Charitable contributions	2,130	1,321
Intangibles	182,441	193,106
Gross deferred tax assets	28,207,953	18,931,779
Less valuation allowance	(27,687,487)	(18,557,844)
Total deferred tax assets	520,466	373,935
Deferred tax liabilities:		
Prepaids	$ (520,466)	$ (373,935)
Gross deferred tax liabilities	(520,466)	(373,935)
Deferred tax assets, net	$ —	$ —

The Company does not have unrecognized tax benefits as of December 31, 2025 or 2024. 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, 2025, 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 $9.1 million during the year ended December 31, 2025.

As of December 31, 2025, the Company had NOL carryforwards of approximately $16.6 million and $4.8 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 NOLs arising in tax years beginning after 2017, however, federal NOLs post 2017 have no expiration.

As of December 31, 2025, the Company also had federal and state research credit carryforwards of $2.3 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 concluded there have been no historical section 382 ownership changes, thus the NOL carryforwards were not subject to an annual limitation through December 31, 2023. The Company has not conducted a study since December 31, 2023 to assess whether a change of control has occurred. If the Company has experienced a change of control, as defined by Section 382, subsequent to the last study, utilization of the net operating loss carryforwards or research and development tax credit carryforwards could be subject to an annual limitation under Section 382. 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, 2025 and 2024.

A reconciliation of income tax benefit at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements as of December 31, 2025:

	2025	
	Amount	**Percentage**
Rate reconciliation:		
US Federal statutory tax rate	$ (5,671,648)	21.0%
State and local income tax, net of federal (national) income tax effect (a)	—	—%
Tax credits	(1,121,821)	4.2%
Changes in valuation allowances	6,188,171	(22.9)%
Nontaxable or nondeductible items	605,298	(2.3)%
Total provision	—	0.0%

(a) State taxes in Illinois and Massachusetts made up the majority of the tax effect in this category

During the year ended December 31, 2025, the Company did not pay any federal income taxes. Additionally, the amount paid in state income taxes, net of refunds received, was immaterial for the year ended December 31, 2025.

On July 4, 2025, the US government enacted the OBBBA, which includes, among other provisions, changes to the US corporate income tax system including the allowance of immediate expensing of qualifying research and development expenses and permanent extensions of certain provisions within the Tax Cuts and Jobs Act. The Company has analyzed the impacts of the OBBBA and reflected them in the current period, resulting in a decrease to the deferred tax asset and valuation allowance of approximately $18.0 million gross ($5.1M tax effected) due to immediate expensing of domestic research and development expenditures.

Note 12. Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the CODM, or decision-making group, in deciding how to allocate resources in assessing performance. CervoMed Inc. has one reportable segment which consists of the development of clinical and nonclinical product candidates for treatments for age-related neurologic disorders and other medical indications. The Company's CODM is the Chief Executive Officer.

The accounting policies of the Company's single segment are the same as those described in the summary of significant accounting policies. To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. The CODM assesses the financial performance for the Company's segment based on net loss. The CODM also uses internal budget versus forecasted expense and cash forecast models in making certain decisions. Such models are reviewed to assess the entity-wide/single-segment operating results and performance, including how long cash-on-hand is expected to be sufficient. The measure of segment assets is reported on the consolidated balance sheet as total assets. The segment measure of loss is reported on the consolidated statement of operations and comprehensive loss as net loss.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the year ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Grant revenue	$ 4,006,510	$ 9,737,974
Research and development expenses:		
Dementia with Lewy bodies	7,052,512	12,102,842
Frontotemporal disorders (incl. nfvPPA)	1,217,784	36,853
Recovery after stroke	1,427,966	391,659
Other clinical* and nonclinical	2,504,863	2,499,202
Personnel costs, excluding stock-based compensation	5,745,558	2,187,221
Stock-based compensation	482,669	218,822
Other research and development expenses, including CMC**	3,385,720	1,361,744
Total research and development expenses	21,817,072	18,798,343
General and administrative expenses:		
Personnel costs, excluding stock-based compensation	4,988,705	3,995,114
Stock-based compensation	965,965	1,186,900
Professional fees	2,752,710	2,684,386
Insurance, taxes and similar fees	1,166,374	985,481
Other general and administrative expenses, including IT, facilities, supplies and similar costs***	610,561	314,879
Total general and administrative expenses	10,484,315	9,166,760
Other income	1,328,510	1,936,436
Net loss	$ (26,966,367)	$ (16,290,693)

* - Includes early-stage clinical studies that are not indication-specific and related costs.

** - Includes, among other things, CMC-related costs, shipping, packaging and storage costs, certain consulting costs, and other miscellaneous research development expenses.

*** - Includes, among other things, costs related to IT systems, rent and other facilities, office supplies, and similar costs.

Note 13. Subsequent Events

The company evaluated subsequent events from December 31, 2025 to the date the financial statements were issued, noting no events requiring disclosure.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15I and 15d-15(e) promulgated under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we are required to apply our judgment in evaluating the cost-benefit relationship of possible internal controls. Our management evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective as of December 31, 2025.

Attestation Report of the Independent Registered Public Accounting Firm

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. As a "smaller reporting company" (as such term is defined in Rule 12b-2 of the Exchange Act), pursuant to Section 989G of the Dodd-Frank Act, we are exempt from the requirement subjecting management's report to attestation by our independent registered public accounting firm.

Change in Internal Control Over Financial Reporting

Remediation of Previously Identified Material Weakness

In connection with the audit of our consolidated financial statements for the years ended December 31, 2024, 2023, and 2022, a material weakness in our internal control over financial reporting was identified in relation to the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. The identified material weakness, if not remediated, could result in a material misstatement to our consolidated financial statements that may not be prevented or detected. A material weakness will not be considered remediated until a remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and it has been concluded, through testing, that the newly implemented and enhanced controls are operating effectively.

On August 16, 2023, we completed the Merger. For financial reporting purposes, EIP was determined to be the accounting acquirer and, accordingly, for all periods prior to the Merger, EIP's historical financial statements and results of operations replace and are deemed to be our financial statement and results of operations for such periods. While Diffusion was previously subject to the provisions of the Sarbanes-Oxley Act of 2002, EIP, as a private, non-reporting operating company prior to the Merger, was not. Accordingly, upon consummation of the Merger, we began the process of integrating the pre-Merger business of EIP into Diffusion's pre-established public company, internal control framework, including internal controls and information systems and we continued to implement measures designed to improve our internal control over financial reporting to remediate the remaining material weakness through the year ended December 31, 2025. During the three-month period ended December 31, 2025, we completed our remediation plan with respect to the material weakness.

Except as set forth above, there were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f)) that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Adoption, Termination or Modification of Trading Arrangements

During the year ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act), adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The additional information required by Item 10 of Form 10-K is incorporated herein by reference from our Proxy Statement, to be filed with the SEC within 120 days after December 31, 2025, the end of the fiscal year to which this Annual Report relates, including the information set forth under the captions, "*Corporate Governance*," "*Delinquent Section 16(a) Reports*," "*Election of Directors*," "*Executive Officers*," and "*Certain Relationships and Related Party Transactions*."

ITEM 11. EXECUTIVE COMPENSATION

The additional information required by Item 11 of Form 10-K is incorporated herein by reference from our Proxy Statement, to be filed with the SEC within 120 days after December 31, 2025, the end of the fiscal year to which this Annual Report relates, including the information set forth under the captions, "*Executive Compensation*," "*Director Compensation*," "*Compensation Committee Report*," and "*Corporate Governance – Compensation Committee Interlocks and Insider Participation*."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The additional information required by Item 12 of Form 10-K is incorporated herein by reference from our Proxy Statement, to be filed with the SEC within 120 days after December 31, 2025, the end of the fiscal year to which this Annual Report relates, including the information set forth under the caption, "*Security Ownership of Certain Beneficial Owners and Management*."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The additional information required by Item 13 of Form 10-K is incorporated herein by reference from our Proxy Statement, to be filed with the SEC within 120 days after December 31, 2025, the end of the fiscal year to which this Annual Report relates, including the information set forth under the captions, "*Corporate Governance*" and "*Certain Relationships and Related Party Transactions*."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The additional information required by Item 14 of Form 10-K is incorporated herein by reference from our Proxy Statement, to be filed with the SEC within 120 days after December 31, 2025, the end of the fiscal year to which this Annual Report relates, including the information set forth under the caption, "*Ratification of Selection of Independent Registered Public Accounting Firm*."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Our financial statements are included in *Part II, Item 8* of this Annual Report.

(b) All financial statement schedules have been omitted from this Item 15 as the required information is not applicable, is not present in amounts sufficient to require submission of such schedules, or because the information required is included in our financial statements or the related notes included in *Part II, Item 8* of this Annual Report.

(c) The exhibits set forth in the following "Index to Exhibits" are filed with, furnished with, and/or incorporated by reference into this Annual Report, as set forth therein. A copy of any of such exhibit will be furnished at a reasonable cost, upon receipt from any person of a written request for any such exhibit. Such request should be sent to CervoMed Inc., 20 Park Plaza, Suite 424, Boston, Massachusetts 02116, Attention: General Counsel.

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 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.
4.2	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.
4.3	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.
4.4	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
4.5	Specimen Stock Certificate	Incorporated by reference to Exhibit 4.15 to the Company's Annual Report on Form 10-K filed on March 29, 2024.

4.6	Description of Securities of CervoMed Inc.	Incorporated by reference to Exhibit 4.16 to the Company's Annual Report on Form 10-K filed on March 29, 2024.
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, effective as of April 16, 2025, by and between Kelly Blackburn, MHA, and CervoMed Inc.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2025.
10.3#	Employment Agreement, effective as of May 1, 2025, by and between Mark De Rosch, PhD, FRAPS, and CervoMed Inc.	Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 18, 2025
10.4#	Amended & Restated Employment Agreement, effective as of June 1, 2024, by and between William Elder and CervoMed Inc.	Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2024.
10.5#	Employment Agreement, effective as of October 6, 2025, by and between Matthew Winton and CervoMed Inc.	Filed herewith.
10.6#	CervoMed Inc. 2025 Equity Incentive Plan	Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2025.
10.7#	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.
10.8#	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.
10.9#	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.
10.10#	Form of Stock Option Award Agreement under 2025 Equity Incentive Plan	Filed herewith.
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 filed on March 29, 2024.
10.12#	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.
10.13#	Form of Inducement Stock Option Award Agreement	Incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 17, 2025.

10.14*	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.
10.15*	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.
10.16*	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.
10.17	Sales Agreement, by and between the Company and Leerink Partners, LLC, dated May 12, 2025	Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on May 12, 2025.
10.18	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	Incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed on May 10, 2024.
10.19#	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 filed on March 29, 2024.
10.20#	Separation Agreement, by and between the Company and Robert J. Cobuzzi, PhD, dated July 1, 2025	Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2025.
19.1	CervoMed Inc. Insider Trading Policy, effective as of March 14, 2025	Incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed on March 17, 2025.
21.1	Subsidiaries of CervoMed Inc.	Incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on March 17, 2025.
23.1	Consent of RSM US LLP, independent registered public accounting firm	Filed herewith.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Acting Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Principal Executive Officer Pursuant to 18 USC. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of CervoMed Inc. under the Securities Act or the Exchange Act, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

32.2	Certification of Acting Principal Financial Officer Pursuant to 18 USC. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	The certification attached as Exhibit 32.2 that accompanies this Annual Report on Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of CervoMed Inc. under the Securities Act or the Exchange Act, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.
97.1	CervoMed Inc. Clawback Policy	Incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on March 29, 2024.
101	The following materials from the Company's annual report on Form 10-K for the year ended December 31, 2025, 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).	

#	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 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 13, 2026

CERVOMED INC.
By: /s/ John Alam, MD
John Alam, MD
President, Chief Executive Officer and Director
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name and Signature	Title	Date
/s/ John Alam, MD John Alam, MD	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2026
/s/ William Elder William Elder	Chief Financial Officer and General Counsel (Principal Financial Officer)	March 13, 2026
/s/ Joshua S. Boger, PhD Joshua S. Boger, PhD	Chair of the Board	March 13, 2026
/s/ Sylvie Grégoire, PharmD Sylvie Grégoire, PharmD	Director	March 13, 2026
/s/ Jane H. Hollingsworth, JD Jane H. Hollingsworth, JD	Director	March 13, 2026
/s/ Jeffrey V. Poulton Jeffrey V. Poulton	Director	March 13, 2026
/s/ David Quigley David Quigley	Director	March 13, 2026
/s/ Marwan Sabbagh, MD Marwan Sabbagh, MD	Director	March 13, 2026
/s/ Frank Zavrl Frank Zavrl	Director	March 13, 2026