UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

December 10, 2024
Date of Report (Date of earliest event reported)

CervoMed Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37942**	**30-0645032**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
20 Park Plaza, Suite 424 Boston, Massachusetts		**02116**
(Address of principal executive offices)		**(Zip Code)**

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

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	CRVO	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

Press Release

On December 10, 2024, CervoMed Inc. (the "Company") issued a press release announcing topline data from its RewinD-LB Phase 2b clinical trial in patients with dementia with Lewy bodies. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Corporate Presentation

Certain information concerning the business, clinical studies, development plans, financial position and related matters of the Company has been made available on our website, www.cervomed.com, under the heading, "Investors – Events and Presentations" and a copy of which is attached as Exhibit 99.2 hereto. Representatives of the Company may use this presentation, in whole or in part, and possibly with non-material modifications, periodically in connection with conferences, meetings, and presentations to investors, analysts and others.

The information contained in the presentation is summary information that is intended to be considered in the context of the Company's filings with the U.S. Securities and Exchange Commission ("SEC") and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in the presentation except as required by applicable law, although the Company may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosure. The Company makes no admission or representation as to the materiality of any information in the presentation or otherwise contained in Item 7.01 of this Current Report on Form 8-K.

The information in this Item 7.01 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

The information set forth in the first, third, and fifth paragraphs of the Company's press release referred to in Item 7.01 above is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 7.01 is furnished and not filed:

Exhibit No.	Description
99.1	Press Release, issued December 10, 2024.
99.2	Corporate Presentation of CervoMed Inc. dated December 10, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Date: December 10, 2024

CervoMed Inc.

By: /s/ William Elder
Name: William Elder
Title: Chief Financial Officer & General Counsel

CervoMed Announces Topline Data from RewinD-LB Phase 2b Clinical Trial in Patients with Dementia with Lewy Bodies

—Neflamapimod did not demonstrate statistically significant effects versus placebo on primary and secondary endpoints at 16 weeks—

—Favorable safety and tolerability results with no new safety signal identified—

—Target plasma drug concentrations not achieved during 16-week double-blind phase of the trial—

—Trial participants continue to receive neflamapimod during open-label extension—

Boston, December 10, 2024 – CervoMed Inc. (NASDAQ: CRVO) ("CervoMed" or the "Company"), a clinical-stage company focused on developing treatments for age-related neurologic disorders, today announced topline data from the RewinD-LB Phase 2b clinical trial evaluating neflamapimod for the treatment of patients with dementia with Lewy bodies (DLB). The trial did not meet statistical significance thresholds for its primary endpoint of change in the Clinical Dementia Rating Sum of Boxes (CDR-SB) or any of its key secondary endpoints – change from baseline in Timed Up and Go (TUG) test, change from baseline in a Neuropsychological Test Battery (NTD) and the Clinician's Global Impression of Change (CGIC). Initial analysis shows that target plasma drug concentrations were not achieved during the double-blind phase of the trial, which may have adversely impacted trial results.

"Obviously, we are disappointed with these results, particularly given our prior clinical experience with neflamapimod in patients with early-stage DLB and we are investigating the reasons for the lower-than-expected plasma drug concentrations. We continue to believe neflamapimod may have potential as a treatment for DLB, and we will thoroughly analyze the clinical and pharmacokinetic data from the trial to better understand its outcome and potential future development paths for the drug. This includes data expected to be available in the first half of 2025 from the first 16 weeks of the open label extension trial which we believe may be valuable to our investigation. In the meantime, we are pausing all preparations for our previously planned Phase 3 trial in early-stage DLB until the full analysis is complete," said John Alam, MD, Chief Executive Officer of CervoMed.

In the RewinD-LB Phase 2b trial, neflamapimod demonstrated a favorable safety and tolerability profile that is consistent with prior clinical studies, with no new safety signal identified.

"We are grateful to the entire DLB community, including trial participants, their caregivers and families, and all of our investigators, sites and coordinators," said Kelly Blackburn, CervoMed's SVP of Clinical Development.

The full data set from the double-blind phase of the RewinD-LB trial is expected to be available to the Company in January 2025 and the data from the first 16 weeks of the open label extension portion of the trial are expected to be available in the late second quarter of 2025. CervoMed will announce the timing of any presentation of additional data from the RewinD-LB trial at a later date upon completion of the first 16 weeks of the open label extension portion of the trial and CervoMed's analysis of all such data.

About Dementia with Lewy Bodies (DLB)

DLB is the third most common degenerative disease of the brain (after Alzheimer's disease and Parkinson's disease), with approximately 700,000 individuals affected in each of the United States (U.S.) and European Union. Patients with this disease accumulate protein deposits, called Lewy bodies, in the brain's nerve cells. This negatively affects cognitive ability, including attention, judgement, and reasoning, along with motor function. Patients with DLB incur higher healthcare costs, have longer hospitalizations, report lower quality of life, and have caregivers with higher levels of distress when compared to patients with Alzheimer's disease. No treatments for DLB have been approved by the U.S. Food and Drug Administration (FDA) or European Medicines Agency, and there are few drugs in development. The current standard of care is cholinesterase inhibitor therapy, which is approved for use in Alzheimer's disease, but in DLB patients typically improves cognition transiently, and does not impact the motor component of the disease.

About Neflamapimod

Neflamapimod is an investigational, orally administered small molecule brain penetrant drug designed to inhibit alpha isoform of the p38MAP kinase. Following preclinical studies in which neflamapimod reversed synaptic dysfunction, results from CervoMed's AscenD-LB Phase 2a clinical trial demonstrated that, compared to placebo, treatment with neflamapimod 40 mg TID significantly improved dementia severity, functional mobility and performance on a cognitive test battery, with the treatment response most substantial among patients with early-stage DLB. With a design guided by learnings from AscenD-LB, CervoMed's RewinD-LB trial was the first trial to successfully enroll an exclusively early-stage DLB patient population.

About the RewinD-LB Phase 2b Trial in Dementia with Lewy Bodies

CervoMed's Phase 2b trial, RewinD-LB, is a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID) in 159 patients with early-stage DLB. In early-stage DLB patients – who are estimated to comprise more than 50% of the total diagnosed DLB patient population at any given time – the disease has not progressed to a point where the patient has significant neuronal loss in the hippocampus. Patients with advanced DLB – in whom there is a significant, irreversible neuronal loss in the hippocampus and associated Alzheimer's Disease co-pathology – were excluded from the trial. The primary endpoint in the trial is a change in CDR-SB, and secondary endpoints include the TUG test, a cognitive test battery, and the CGIC. The RewinD-LB trial is funded by a $21.3 million grant from the National Institutes of Health's National Institute on Aging, which is being disbursed over the course of the trial as costs are incurred. The trial includes 43 sites across the United States, the United Kingdom, and the Netherlands).

About CervoMed

CervoMed Inc. is a clinical-stage company focused on developing treatments for age-related neurologic disorders. The Company is currently developing neflamapimod, an investigational, orally administered small molecule brain penetrant designed to inhibit p38 mitogen-activated protein kinase alpha. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that causes disease in certain major neurological disorders.

Forward-Looking Statements

This press release includes express and implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, regarding the intentions, plans, beliefs, expectations or forecasts for the future of the Company, including, but not limited to, the therapeutic potential of neflamapimod in DLB or any other indication; the anticipated timing and achievement of clinical and development milestones, including the announcement of additional data from the RewinD-LB trial, any meeting with the FDA, the initiation of any future clinical trials, or the commercial approval, if any, of neflamapimod by the FDA or any other regulatory authority; any other expected or implied benefits or results, including that any initial clinical results observed with respect to neflamapimod in the AscenD-LB Trial or RewinD-LB Trial will be replicated in later trials; and the results of the Company's ongoing investigation of the lower than expected blood concentration levels observed in the double-blind portion of the RewinD-LB trial. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "aims," "seeks," "intends," "may," "might," "could," "might," "will," "should," "approximately," "potential," "target," "project," "contemplate," "predict," "forecast," "continue," or other words that convey uncertainty of future events or outcomes (including the negative of these terms) may identify these forward-looking statements. Although there is believed to be reasonable basis for each forward-looking statement contained herein, forward-looking statements by their nature involve risks and uncertainties, known and unknown, many of which are beyond the Company's control and, as a result, actual results could differ materially from those expressed or implied in any forward-looking statement. Particular risks and uncertainties include, among other things, those related to: the Company's available cash resources and the availability of additional funds on acceptable terms; the results of the Company's clinical trials, including RewinD-LB; the likelihood and timing of any regulatory approval of neflamapimod or the nature of any feedback the Company may receive from the U.S. Food and Drug Administration; the ability to implement business plans, forecasts, and other expectations in the future; general economic, political, business, industry, and market conditions, inflationary pressures, and geopolitical conflicts; and the other factors discussed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the U.S. Securities and Exchange Commission (SEC) on March 29, 2024, and other filings that the Company may file from time to time with the SEC. Any forward-looking statements in this press release speak only as of the date hereof (or such earlier date as may be identified). The Company does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except to the extent required by law.

Investor Contact:

PJ Kelleher
LifeSci Advisors
Investors@cervomed.com
617-430-7579

Media Contact:

Emma Yang
Health+Commerce
cervomed@healthandcommerce.com
908-391-7197

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Medicines for the Brain

Corporate Overview

December 2024

NASDAQ: CRVO

Forward-Looking Statements

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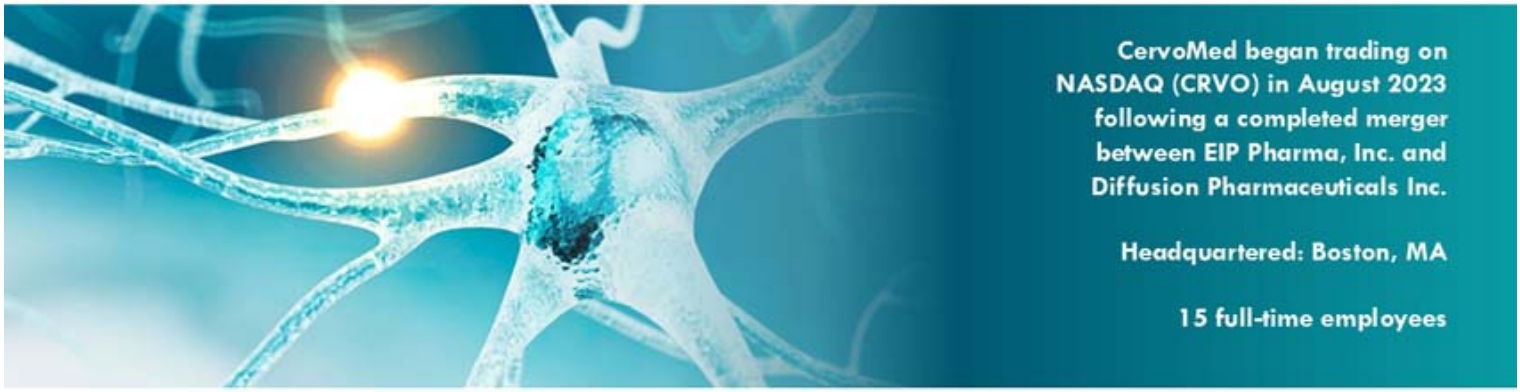
Company Overview

Targeting the Early Stage of the Neurodegenerative Process, Synaptic Dysfunction, to Treat Age-Related Neurologic Disorders



CervoMed began trading on NASDAQ (CRVO) in August 2023 following a completed merger between EIP Pharma, Inc. and Diffusion Pharmaceuticals Inc.

Headquartered: Boston, MA

15 full-time employees

Lead Asset: Neflamapimod licensed from Vertex Pharmaceuticals; developed for CNS indications by EIP Pharma/CervoMed

Neflamapimod IP covered by multiple CervoMed-owned issued patents around method of use for various indications and formulations, expiring at various dates through 2039

Experienced Leadership Team

John Alam, MD

President, CEO & Co-Founder, Director

Former Chief Medical Officer and EVP Medicines Development, Vertex

Former Global Head Alzheimer's R&D at Sanofi

Led clinical development of Avonex for multiple sclerosis at Biogen

William Elder

Chief Financial Officer & General Counsel

Principal Financial Officer of CervoMed since March 2024

General Counsel and Corporate Secretary of Diffusion (2020-23)

J.D. from University of Pennsylvania School of Law, M.S. Finance from Villanova University, B.A. Economics from Tufts University

Robert J. Cobuzzi Jr., PhD

Chief Operating Officer, Director

President, Chief Executive Officer and Director of Diffusion (2020-23)

More than 25 years of cross-functional leadership and operational experience in pharmaceutical and biotechnology companies, including Endo, Adolor, Centocor and AstraMerck

Kelly Blackburn, MHA

SVP, Clinical Development

Former VP, Clinical Affairs at aTyr Pharma; VP, Clinical Development Operations at Vertex. Led global clinical operations for Kalydeco® for the treatment of cystic fibrosis, Incivek® for hepatitis C, and Velcade® for multiple myeloma

DIRECTORS

Joshua Boger, PhD (Chair)
Executive Chair, Alkeus Therapeutics.
Founder, former CEO, Vertex Pharmaceuticals

Sylvie Gregoire, PharmD
Co-Founder; Board member, Novo Nordisk, F2G, Abivax; Former Executive VP, Biogen; Former President, HGT Division, Shire Pharmaceuticals; Former Board member, Revitty, ViFor, Corvidia, Cubist

Jeff Poulton (Chair of Audit Committee)
CFO, Alnylam Pharmaceuticals (Nasdaq:ALNY)
Former CFO, Shire Pharmaceuticals; CFO, Indigo Agr.

Jane H. Hollingsworth, JD
Managing Partner, Militia Hill Ventures
Former Chairman of the Board, Diffusion Pharmaceuticals

Marwan Sabbagh, MD
Prof. of Neurology at the Alzheimer's and Memory Disorders division of the Barrow Neurological Institute at Dignity Health/St Joseph's Hospital in Phoenix, Arizona

Frank Zavrl
Former Board Member, Puma Biotechnology
Retired Partner, Adage Capital

SCIENTIFIC ADVISORS

Ole Isacson, MD (Chair)
Prof of Neurology (Neuroscience) Harvard Medical School

Lewis Cantley, PhD
Professor of Cell Biology, Harvard Medical School, Dana-Farber Cancer Institute; Laureate, Breakthrough Prize in Life Sciences

Jeff Cummings, MD, PhD
Director, Chambers-Grundy Center for Transformative Neuroscience at UNLV

Heidi McBride, PhD
Professor, Dept. of Neurology & Neurosurgery, McGill University

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Financial Overview[1]

CervoMed has an expected cash runway into mid-2026[2]

Cash Resources and Grant Funding

- $46.7M in cash, cash equivalents and marketable securities as of September30, 2024
- $21.3M NIA Grant originally awarded January '23, disbursed over course of RewinD-LB trial
  - $6.2M in remaining NIA grant funding yet to be received

Capitalization

- 8.3 million shares outstanding
- 2.5 million shares underlying outstanding Series A warrants
  - Exercise Price = $39.24

1. Unless otherwise indicated, all financial information is approximate and as of September 30, 2024. For additional, important information regarding the Company's financial position and results of operations, please refer to the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, filed with the SEC on November 12, 2024.
2. Based on the Company's current operating plan as of December 9, 2024, and inclusive of the remaining funds to be received from the NIA Grant. The Company has based this estimate on assumptions that may prove to be wrong and it could utilize its available capital resources sooner than it currently expects.

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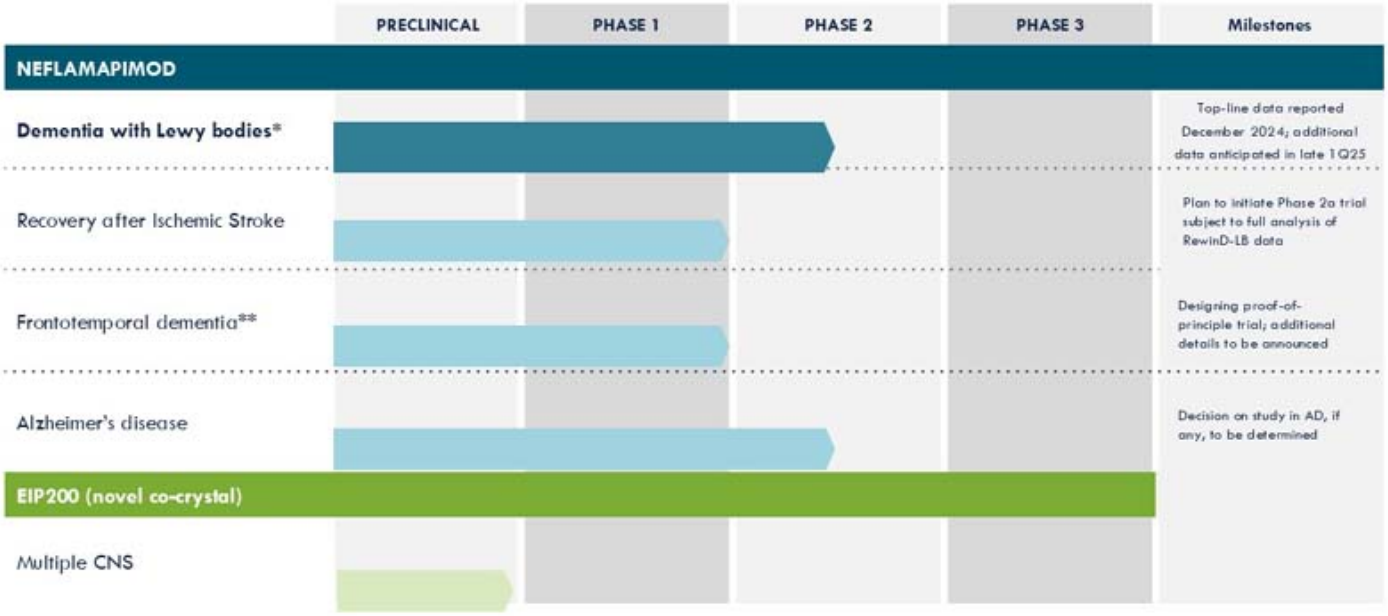
CervoMed Pipeline



Worldwide commercial rights across programs
*Received FDA Fast Track designation
**Received FDA Orphan Drug designation

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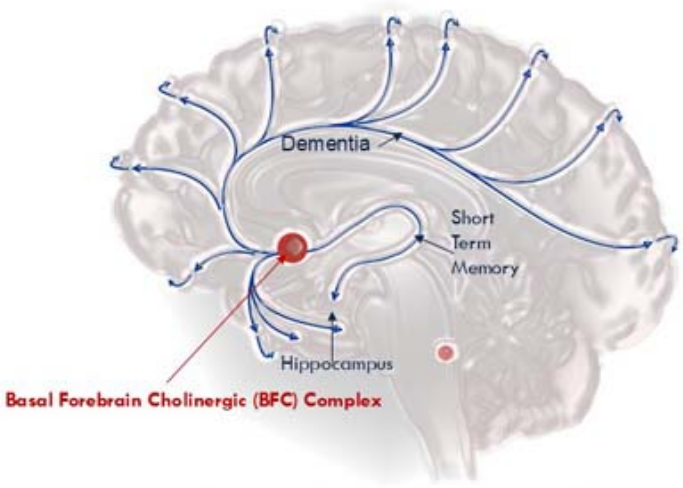
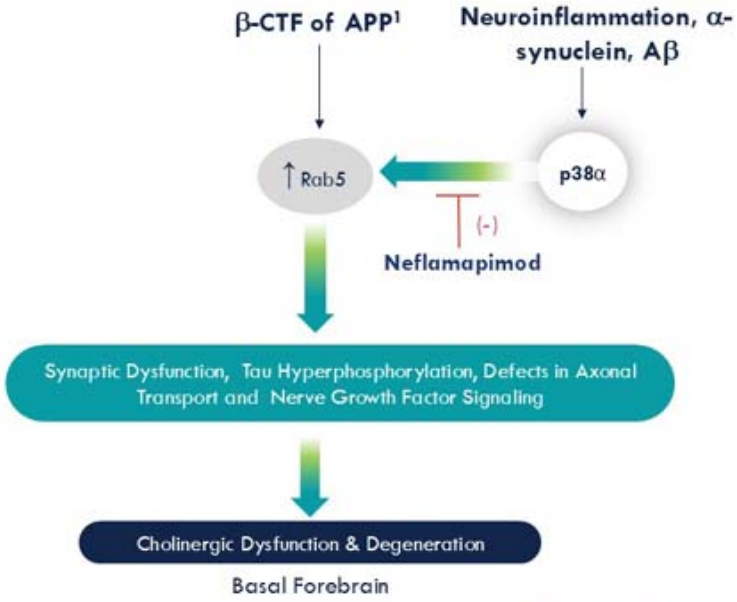
Neflamapimod Mechanism of Action

Oral p38a Kinase Inhibitor Targeting Cholinergic Dysfunction and Degeneration



Release of acetylcholine through cortical connections modulates cognitive and motor tasks



NGF: Nerve Growth Factor

Adapted from Alam & Nixon, *Molecular Neurodegeneration*, 2023. 1. APP: Amyloid Precursor Protein

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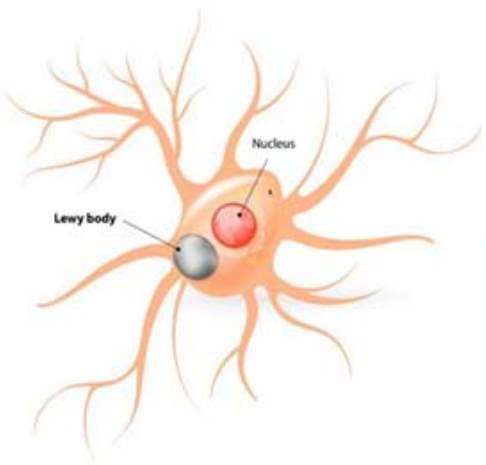
Dementia with Lewy Bodies (DLB)



DLB associated with abnormal deposits ("Lewy bodies") within neurons of a protein called alpha-synuclein in the brain.

Primary site of pathology is basal forebrain

Clinically, characterized by dementia and ≥ 2 of the following: fluctuating attention, visual hallucinations, REM sleep disorder, and/or parkinsonism (motor deficits)[1]

- DLB patients experience rapid clinical worsening, high healthcare costs, low quality of life, and caregivers have high levels of distress. DLB patients progress significantly faster than patients with Alzheimer's disease (AD)

Treatment Landscape and Unmet Need

- **No approved therapies;** limited drugs in development
- Current standard of care is cholinesterase inhibitor therapy; only transiently improves cognition & does not impact motor component

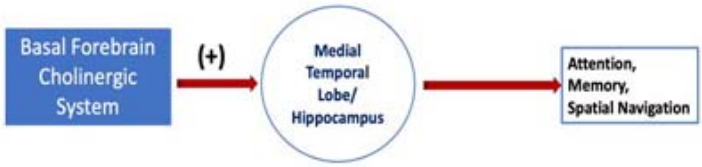
Market Opportunity

- **3rd most common degenerative disease of the brain** (after AD and PD)
- **1.4M individuals in US and EU**

1. https://www.nia.nih.gov/health/what-lewy-body-dementia-causes-symptoms-and-treatments

Clinical Course of DLB Creates Unique Opportunities for Therapeutic Intervention

	Basal Forebrain Cholinergic System	Temporal Lobe (Hippocampus)	Ability to Partially Restore Function	Alzheimer's disease (AD) related biomarker	Prevalence
Early-Stage DLB	Diseased	**Spared**	**Yes, with a drug targeting disease in the cholinergic system**	**Not elevated**	**Approximately 50% of all patients with DLB[1]**
Advanced DLB	Diseased	Significant Neurodegeneration	Limited by Temporal Lobe Neurodegeneration	Elevated	Approximately 50% of all patients with DLB[1]



[1] Jain et al, 2024, Bolseweig et al, 2024

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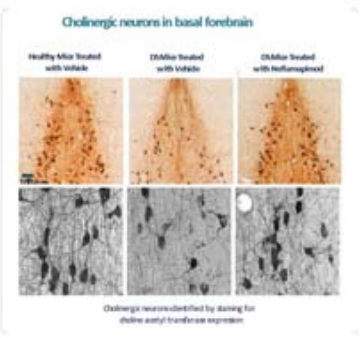
Neflamapimod: Targeted Therapy for Diseases of the Basal Forebrain

Preclinical — ***Disease processes in basal forebrain reversed with neflamapimod***

When administered in mice that develop basal forebrain cholinergic degeneration, neflamapimod:

- ✓ Reduced Rab5 activity and tau phosphorylation
- ✓ Reversed loss of cholinergic (ChaT+) neurons in the basal forebrain; and
- ✓ Normalized performance in behavioral tests of cholinergic function[2]



Clinical — ***Improvement on multiple clinical endpoints in Phase 2a trial***

In AscenD-LB, a 91-patient, 16-week, placebo-controlled Phase 2a trial in patients with DLB neflamapimod:

- ✓ Significantly improved dementia severity (assessed by Clinical Dementia Rating Sum-of Boxes, CDR-SB, p=0.023 vs. placebo)
- ✓ Significantly improved gait (assessed by Timed Up and Go, TUG, p=0.044 vs. placebo
- ✓ Reduced levels of plasma biomarker of neurodegeneration (glial fibrillary acidic protein (GFAP))
- ✓ Results most prominent in patients with Early-Stage DLB

1. Alam & Nixon, *Molecular Neurodegeneration*, 2023. 2. Nature Communications, 13: 5308 (2022). https://www.nature.com/articles/s41467-022-32944-3

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RewinD-LB Phase 2b in Early-Stage DLB

TRIAL OVERVIEW

DLB by consensus criteria

Pre-treatment plasma ptau181 <2.4 pg/ml

N= 159 participants

Blinded, randomized 1:1 to neflamapimod or matching placebo

16-week primary analysis, followed by 32-week open-label neflamapimod treatment extension

KEY OUTCOME MEASURES

Primary: Clinical Dementia Rating Sum of Boxes (CDR-SB)

Secondary: Timed Up and Go (TUG) test, Neuropsychological Test Battery (NTB), Clinical Global Impression of Change (CGIC)

EEG: beta functional connectivity (primary), eyes-closed to eyes-open alpha reactivity

MRI: atrophy of basal forebrain, and its functional connectivity

Plasma biomarker: GFAP

RewinD-LB Topline Data Summary

- Neflamapimod did not demonstrate statistically significant effects versus placebo on primary and secondary endpoints at 16 weeks
- Target plasma drug concentrations not achieved during the double-blind phase of the trial; investigation of cause ongoing
- Favorable safety and tolerability results with no new safety signal identified
- Additional data, including data from the initial 16-week portion of the open-label extension, expected in 1H25

CERVOMED

Medicines for the Brain

Corporate Overview

December 2024

NASDAQ: CRVO