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

September 6, 2023
Date of Report (Date of earliest event reported)

CervoMed Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-24477**	**30-0645032**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
20 Park Plaza, Suite 424 Boston, Massachusetts		**02216**
(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 8.01. Other Events

Press Release

On September 6, 2023, CervoMed Inc. (the "Company," "we" or "us") issued a press release announcing the publication online in Neurology®, the medical journal of the American Academy of Neurology, of additional pre-specified analyses of the Company's AscenD-LB Phase 2a clinical trial showing an association between plasma phosphorylated tau at position 181 levels at study entry and patient's response to neflamapimod in the treatment of dementia with Lewy Bodies. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Corporate Presentation

A presentation containing certain information concerning the Company's business, clinical studies, development plans, and related matters has been made available on the Company's website, www.cervomed.com, under the heading, "Investors - Events and Presentations." A copy of the presentation is also attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. 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, including the H.C. Wainwright 25th Annual Global Investment Conference beginning September 11, 2023.

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 Securities and Exchange Commission ("SEC") and other public announcements that it 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated September 6, 2023
99.2	Corporate Presentation, dated September 6, 2023
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: September 6, 2023

CervoMed Inc.

By: /s/ William Elder
Name: William Elder
Title: General Counsel

CervoMed Announces Publication in *Neurology*® Results Showing a Blood Test at Study Entry Identified Patients Who Demonstrated Substantial Response to Neflamapimod in Dementia with Lewy Bodies

Additional protocol-specified analyses of the AscenD-LB Phase 2a results show that patients without elevated plasma ptau181 levels are more responsive than those with such elevation and have substantial treatment benefits to neflamapimod.

BOSTON, MA – Sept 6, 2023 – CervoMed Inc., a clinical stage company focused on developing treatments for degenerative diseases of the brain, today announced the publication online on September 1, 2023, in *Neurology*®, the medical journal of the American Academy of Neurology, of additional pre-specified analyses of the AscenD-LB Phase 2a clinical trial showing an association between plasma phosphorylated tau at position 181 (ptau181) levels at study entry and patient's response to neflamapimod in the treatment of dementia with Lewy Bodies (DLB).

"In the AscenD-LB study, treatment with oral neflamapimod at a dose of 40mg three-times-per-day was associated with significant improvements of dementia severity and functional mobility compared to placebo. After the study was completed, multiple reports were published that showed that the blood-based biomarker plasma ptau181 can identify patients with DLB who harbor Alzheimer's disease related co-pathology, which is associated with a greater degree of brain atrophy and associated neuronal loss. Therefore, as pre-specified in the protocol, we re-analyzed the effects of neflamapimod 40mg three-times-per-day in the AscenD-LB dataset, stratifying the sample according to pre-treatment levels of plasma ptau181. These new results show that while the effects of 16 weeks of treatment with neflamapimod were non-significantly different from placebo in patients with abnormally elevated plasma ptau181, neflamapimod was associated with a statistically significant benefit in patients with normal pre-treatment levels of plasma ptau181, with a treatment effect size of at least 0.7 for each of the measures of dementia severity, attention, recognition memory, and functional mobility," said Stephen Gomperts, MD, PhD, a senior author on the publication, and Director of the Lewy Body Dementia (LBD) Unit at the Massachusetts General Hospital in Boston.

"The results support our long-standing thesis that the key to treating chronic neurodegenerative disease is to intervene early in the disease process, ahead of the patient having extensive neuronal loss in the brain," said John Alam, MD, Chief Executive Officer of CervoMed and first author of the publication. He added, "In the near term, we believe the exclusion of patients with abnormal levels of plasma ptau181 in our ongoing Phase 2b clinical trial of neflamapimod in patients with DLB will substantively increase the probability of success in that clinical trial. In the long-term, blood-based biomarkers such as plasma ptau181 hold the potential to implement a personalized medicine approach to treating the major neurodegenerative diseases to enhance the value delivered to patients."

A water-marked version of the manuscript, entitled "Association of plasma phosphorylated tau with the response to neflamapimod treatment in patients with dementia with Lewy bodies", is available on the *Neurology* website and the full publication, both online and a short version in print, will be published later in the fall. The online publication can be accessed here.

The AscenD-LB Phase 2a Study Results and Analyses as Published in *Neurology*

The AscenD-LB clinical trial was a Phase 2a double-blind, placebo-controlled, 16-week treatment study of neflamapimod in 91 patients with mild-to-moderate DLB (NCT04001517). The main results, which were published in September 2022 in the journal *Nature Communications*, demonstrated that neflamapimod significantly improved dementia severity compared to placebo and also showed significant improvement on motor function compared to placebo; at the highest dose evaluated, neflamapimod also improved cognition. For the *Neurology* publication, as pre-specified in the protocol, after the study was completed (*i.e.*, *post-hoc*), with the availability of information regarding the utility of the assay to identify patients with Alzheimer disease (AD) co-pathology in patients with DLB, pre-treatment plasma ptau181 levels were determined in patients who had at least one on-study efficacy measure and participants were grouped based on a cut-off for AD pathology of 2.2 pg/mL (established in a separate cohort to identify AD from healthy controls). Clinical outcomes for the comparison of placebo with neflamapimod 40mg three-times-daily (TID), the higher and more clinically active of two doses studied, were analyzed utilizing Mixed Models for Repeated Measures within each sub-group (baseline plasma ptau181 < and ≥2.2 pg/mL). The results, as reported in the current publication, showed 45 participants were below, and 40 above, the 2.2 pg/mL cut-off at baseline. Moreover, during the 16-week treatment period, in the comparison of placebo with neflamapimod 40mg TID, for all endpoints evaluated, improvements with neflamapimod treatment were greater in participants below the cut-off, compared with that in those above the cut-off. In addition, participants below the ptau181 cut-off at baseline showed significant improvement over placebo in an Attention Composite measure (+0.42, 95%CI: 0.07–0.78, p=0.023, Cohen's d effect size=0.78), the Clinical Dementia Rating Scale Sum of Boxes (-0.60, 95%CI:-1.04,-0.06, p=0.031, d=0.74), the Timed Up and Go test (-3.1 sec, 95%CI:-4.7,-1.6, p<0.001, d=0.74), and International Shopping List Test-Recognition (+1.4, 95% CI: 0.2–2.5, p=0.024, d=1.00).

About Neflamapimod

Neflamapimod is an investigational drug that is an orally administered small molecule brain penetrant that inhibits p38MAP kinase alpha (p38a). P38a, which is expressed in neurons under conditions of stress and disease, plays a major role in inflammation-induced synaptic toxicity, leading to synaptic dysfunction. Neflamapimod is currently being developed for the treatment of dementia with Lewy bodies (DLB) and is the first treatment with the potential to have a positive impact on cognition, function, and mobility.

In preclinical studies, neflamapimod reversed synaptic dysfunction, including and particularly within the part of the brain most impacted in DLB – the basal forebrain cholinergic system. In Phase 1 and Phase 2 clinical studies involving more than 300 participants, neflamapimod has been shown to be generally well tolerated. Results from the AscenD-LB Phase 2a clinical study demonstrated that neflamapimod significantly improved dementia severity compared to placebo and also showed significant improvement on motor function compared to placebo. At the highest dose evaluated, neflamapimod also improved cognition. The combined preclinical and clinical data are consistent with neflamapimod treating the underlying DLB disease process and suggest that neflamapimod has the potential to be the first disease-modifying treatment for DLB. Neflamapimod was granted Fast Track status by the U.S. Food and Drug Administration for the treatment of DLB, and EIP Pharma Inc. (a wholly owned subsidiary of CervoMed) in January 2023 was awarded a $21 million grant from the National Institutes of Health's National Institute on Aging (NIA) to evaluate neflamapimod in a Phase 2b clinical study in DLB. The NIA grant funds will be disbursed over the course of the ongoing phase 2b study as the costs are incurred.

About CervoMed

CervoMed Inc. is a clinical-stage biotechnology company advancing CNS-focused therapeutics to benefit patients with a range of degenerative diseases of the brain. The Company is currently developing neflamapimod, an investigational orally administered small molecule brain penetrant that inhibits p38MAP kinase alpha (p38a). Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in dementia with Lewy bodies (DLB) and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with DLB. CervoMed was formed in August 2023 after the merger of EIP Pharma Inc with Diffusion Pharmaceuticals Inc. For more information, please visit www.cervomed.com, or follow us on Twitter and LinkedIn.

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 CervoMed Inc. (the "Company"), including, but not limited to, the therapeutic potential of neflamapimod; anticipated milestones related to the development of the Company's clinical programs, including timelines for trial enrollment and reporting of data; the potential results of our ongoing Phase 2b clinical trial of neflamapimod in patients with DLB; and the potential commercial opportunity of neflamapimod, if approved. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes 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 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 Company's ability to maintain its listing on the Nasdaq Capital Market, as well as comply with applicable Nasdaq rules and regulations; the market price of the Company's securities, which may be volatile due to a variety of factors, including changes in the competitive and highly regulated industry in which the Company operates; variations in operating performance across competitors; changes in laws and regulations affecting the Company's business; 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 most recent Annual Report on Form 10-K, in the proxy statement/prospectus/information statement that is included in the Company's registration statement on Form S-4 (File No. 333-271823) that was filed with the SEC, and other filings that the Company may file from time to time with the SEC. Any forward-looking statements in this release speak to the date hereof (or such earlier date as may be identified). New factors emerge from time to time, and it is not possible for the Company to predict all such factors, nor can we assess the impact of each such factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. The Company does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this release, except to the extent required by law.

Contacts
CervoMed Investors & Media:
Argot Partners
212.600.1902
CervoMed@argotpartners.com

CERVOMED

"Medicines for the Brain"

Corporate Overview

NASDAQ: CRVO

cerveau (sair-voh), noun, in French for *brain* or *mind*

Forward-Looking Statements

This presentation 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 CervoMed Inc. (the "Company"), including, but not limited to, the therapeutic potential of neflamapimod; anticipated milestones related to the development of the Company's clinical programs, including timelines for trial enrollment and reporting of data; and the potential commercial opportunity of neflamapimod, if approved. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes 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 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 Company's ability to maintain it's listing on the Nasdaq Capital Market, as well as comply with applicable Nasdaq rules and regulations; the market price of the Company's securities, which may be volatile due to a variety of factors, including changes in the competitive and highly regulated industry in which the Company operates; variations in operating performance across competitors; changes in laws and regulations affecting the Company's business; 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 most recent Annual Report on Form 10-K, in the proxy statement/prospectus/information statement that is included in the Company's registration statement on Form S-4 (File No. 333-271823) that was filed with the SEC, and other filings that the Company may file from time to time with the SEC. Any forward-looking statements in this presentation speak only as of September 6th (or such earlier date as may be identified). New factors emerge from time to time, and it is not possible for the Company to predict all such factors, nor can we assess the impact of each such factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. The Company does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation, except to the extent required by law.

CervoMed at a Glance

Late Clinical Stage CNS Company	Differentiated approach to age-related neurologic disorders with a late-stage lead clinical asset; pipeline of additional indications and second asset
Phase 2b Ready Lead Drug Candidate	Neflamapimod has the potential to be the ***first disease-modifying treatment for dementia with Lewy bodies (DLB)***; positive phase 2a data published in *Nature Communications*; granted Fast Track designation by FDA
Attractive Commercial Opportunity in DLB	1.4M patients in the US and EU; 3rd most common neurodegenerative disease[1] >$3B US peak sales opportunity for first to market
Multiple Catalysts by the end of 2024	First patient dosing Phase 2b DLB clinical study August'23; complete enrollment in 1H24 and report primary efficacy results[2] in 2H24
Phase 2b Clinical Study Fully Funded	Awarded $21M grant from the NIH's National Institute on Aging (NIA) which will fully fund the planned Phase 2b study[3]. CervoMed has cash runway to fund company operations through to primary efficacy readout in the study.

1. After Alzheimer's disease and Parkinson's disease. 2. From placebo-controlled portion of Phase 2b DLB study. 3. The NIA grant funds will be disbursed over the course of study as costs are incurred.

CervoMed Management 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

Robert J. Cobuzzi Jr., PhD – Chief Operating Officer
- President, Chief Executive Officer and Director of Diffusion since 2020
- More than 25 years of cross-functional leadership and operational experience in pharmaceutical and biotechnology industries, including Endo, Adolor, Centocor and AstraMerck

William Tanner, PhD – Chief Financial Officer
- 20 years+ prior experience as a biotech and biopharma research analyst for leading healthcare investment banks including Vector Securities, SG Cowen, Leerink Swann, Lazard Capital Markets and Guggenheim Securities.

William Elder – General Counsel, Corporate Secretary
- General Counsel and Corporate Secretary of Diffusion since 2020
- Nearly a decade of experience advising private and public companies in the pharmaceutical and biotechnology industry with Dechert LLP

Kelly Blackburn – 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

Non-Employee Directors and Advisors

CERVOMED

DIRECTORS

Sylvie Gregoire, PharmD (Chair)
- Former Executive Chair and Co-Founder of EIP Pharma
- Board member, Novo Nordisk, Revity (f/k/a Perkin Elmer), F2G
- Former President, Human Genetics Therapies, Shire
- Former Executive VP, Biogen; CEO, GlycoFi
- Former Board member at Vifor, Cubist, Board Chair at Corvidia

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

Jane H. Hollingsworth, JD
- Managing Partner, Militia Hill Ventures
- Former Chairman of the Board, Diffusion Pharmaceuticals
- Former Executive Chair, Immunome
- Former CEO, NuPathe (Nasdaq:PATH)

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
- Camille and Larry Ruvo Endowed Chair for Brain Health and Director of Translational Research at Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas

Frank Zavrl
- Former Board Member, Puma Biotechnology
- Former Partner, Adage Capital
- Former Research Analyst at Merlin BioMed, Scudder Kemper Investments

Jill Davidson
- President of Fast Scripts LLC and Co-Manager of SkiProp LLC
- Former Vice President at Omnicare, Inc.
- Former Chief Operating Officer of Clasen Long Term Care Pharmacy

SCIENTIFIC ADVISORS

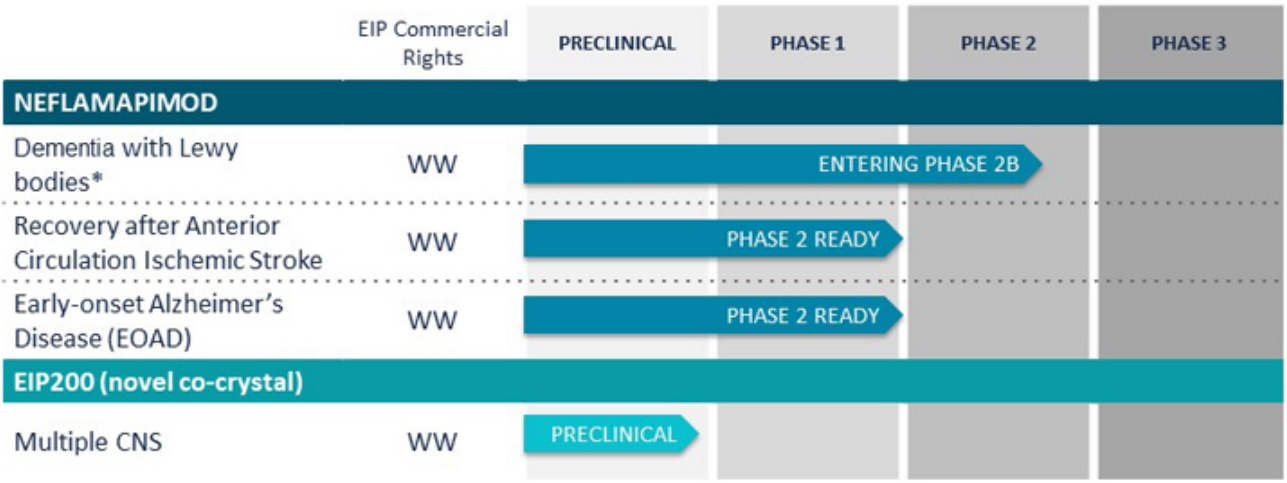
Ole Isacson, MD (Chair)
- Prof of Neurology (Neuroscience) Harvard Medical School

Lewis Cantley, PhD
- Professor of Cell Biology, Harvard Medical School, Dana-Farber Cancer Inst.
- Former Director of the Sandra and Edward Meyer Cancer Center and Professor of Cancer Biology in Medicine at Weill Cornell Medical College
- Co-Founder Petra Pharma, Agios Pharmaceuticals, Volastra Therapeutics

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

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

CervoMed Pipeline



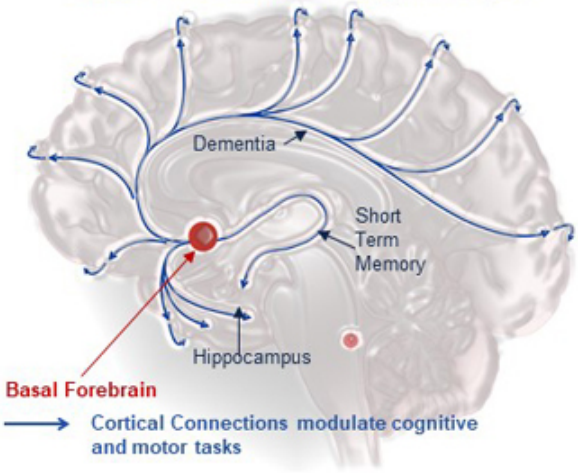
*Received FDA Fast Track designation

Opportunity for Therapeutics Targeting Basal Forebrain Cholinergic Degeneration

CERVOMED

- Age-related degeneration of the basal forebrain cholinergic system plays major role in many neurologic disorders:
  - Dementia with Lewy bodies (DLB), where it is the primary pathology
  - Early stages of Alzheimer's
  - Impaired functional recovery after stroke
  - Gait dysfunction, dementia in Parkinson's
- The neurodegenerative process in the basal forebrain is ***reversible***

Basal Forebrain Cholinergic Complex



Dementia with Lewy Bodies (DLB)

What is DLB?

- Disease associated with abnormal deposits of a protein called alpha-synuclein in the brain. These deposits, called Lewy bodies, affect chemicals in the brain whose changes, in turn, can lead to problems with thinking, movement, behavior, and mood1
- Patients incur greater rate of cognitive decline, higher healthcare costs, report lower quality of life, and have caregivers with higher levels of distress compared to patients with Alzheimer's disease (AD)

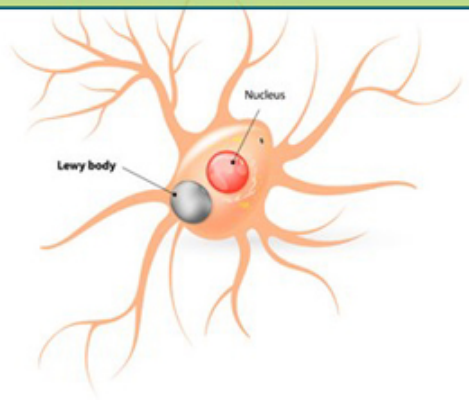
Treatment Landscape and Unmet Need

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

Market Opportunity

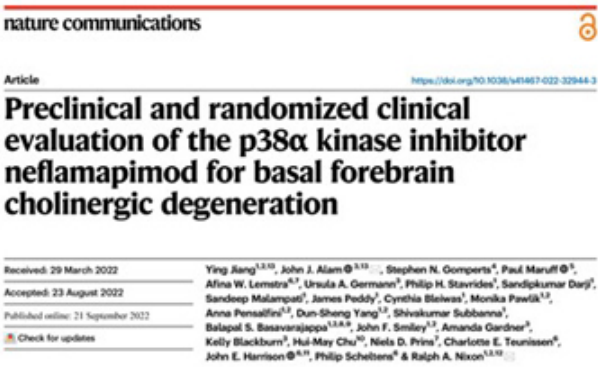
- 3rd most common neurodegenerative disease (after AD and PD)
- ~700,000 individuals in each of US and EU
- Neflamapimod has the potential to be the first disease-modifying approach because it treats the primary pathology - cholinergic degeneration in the basal forebrain

DLB affects ~1.4 million individuals in the US and EU



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

Neflamapimod for DLB: Positioned for Success



nature communications

Article

https://doi.org/10.1038/s41467-022-32944-3

Preclinical and randomized clinical evaluation of the p38α kinase inhibitor neflamapimod for basal forebrain cholinergic degeneration

Received: 29 March 2022
Accepted: 23 August 2022
Published online: 21 September 2022
Check for updates

Ying Jiang[1,2,12], John J. Alam[3,12], Stephen N. Gomperts[4], Paul Maruff[5], Afina W. Lemstra[6,7], Ursula A. Germann[8], Philip H. Stavrides[1], Sandipkumar Darji[1], Sandeep Malampati[1], James Peddy[1], Cynthia Bleiwas[1], Monika Pawlik[1,2], Anna Pensalfini[1,2], Dun-Sheng Yang[1,2], Shivakumar Subbanna[1], Balapal S. Basavarajappa[1,2,9,10], John F. Smiley[1,2], Amanda Gardner[5], Kelly Blackburn[5], Hui-May Chu[10], Niels D. Prins[7], Charlotte E. Teunissen[6], John E. Harrison[8,11], Philip Scheltens[6] & Ralph A. Nixon[1,2,12]

"The authors show in an animal model and in a study in patients with dementia with Lewy bodies (DLB) that the drug neflamapimod has potential to treat diseases, such as DLB, associated with loss of neurons that produce the neurotransmitter acetylcholine."

Nature Communications, 13, Article number: 5308 (2022)

- Mechanism of action that targets the specific diseases processes underlying DLB
- In animal models, neflamapimod reverses, not just slows, the neurodegenerative process
- Safety profile well defined, with clinical safety data in > 300 study participants at daily dose up to 10-fold higher than dose in phase 2b study in DLB
- Phase 2a data showed that neflamapimod significantly improved versus placebo both cognitive and motor aspects of DLB
- First patient dosed in Phase 2b study in DLB designed to confirm phase 2a results in August '23, with data readout expected in H2'24

Neflamapimod ***Reverses*** Cholinergic Dysfunction and Degeneration

Down Syndrome (DS) mice

- Transgenic mice that have both DS-like defects during early development and adult-onset basal forebrain cholinergic degeneration
- Treated with vehicle or 3 mg/kg neflamapimod (NFMD) BID x 28 days, starting at month 6

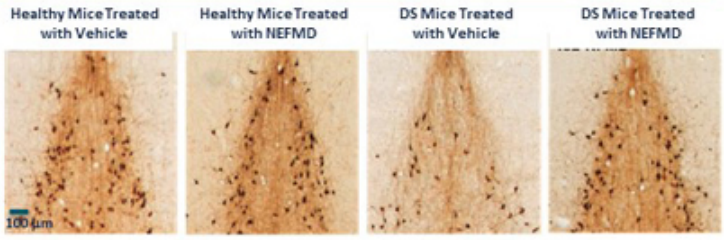
Reversed basal forebrain cholinergic neuron loss and restored cholinergic function

- Significantly increased number of cholinergic neurons in basal forebrain
- Normalized performance in Open field and NOR behavioral tests

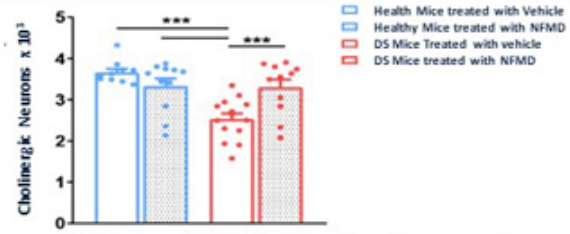
Mechanism of action well defined

- Significantly reduced Rab5 activity and BACE1 / β-CTF protein level
- Reversed Rab5+ endosomal pathology
- Normalized level of phosphorylated p38a and reduced levels of its downstream substrates MK2 and MNK1

Cholinergic neurons in basal forebrain



NFMD-treated DS mice show >30% increase in cholinergic neurons compared to vehicle-treated DS mice (*p<0.001)**



Cholinergic neurons identified by staining for choline acetyl transferase expression

Phase 2a Exploratory Clinical Study in Dementia with Lewy Bodies (DLB)

CERVOMED

AscenD-LB

Patients

- Mild-to-Moderate DLB by consensus criteria (McKeith, *Neurology*, 2017)
- Abnormal dopamine uptake by DaTscan™
- On background cholinesterase inhibitor therapy

16-WEEK TREATMENT, DOUBLE-BLIND
NFMD 40 mg or matching placebo

Outcome Measures

- DLB-specific Neuropsychological Test Battery (NTB, a cognitive test battery)
- Dementia Severity, assessed by CDR-SB
- Motor Function, assessed by Timed Up and Go (TUG) test

Dosing

- **Randomized to neflamapimod (n=46) or placebo (n=45)**
- **Twice daily (BID) if weight < 80kg or three times daily (TID) if weight ≥ 80kg**
- **Well tolerated, with no study drug related discontinuations**

Nature Communications, 13, Article number: 5308 (2022). https://www.nature.com/articles/s41467-022-32944-

AscenD-LB Outcome Measures

Clinical Dementia Rating Sum of Boxes (CDR-SB, Total Score = 0-18)

Cognitive Domains:
- Memory (0-3)
- Orientation (0-3)
- Judgement and Reasoning (0-3)

Functional Domains:
- Community Affairs (0-3)
- Home & Hobbies (0-3)
- Personal Care (0-3)

Timed Up and Go Test (TUG, scored in seconds)

Neuropsychological Test Battery (NTB)*:
- Detection
- Identification
- One Card Learning
- One Back
- Letter Fluency Test
- Category Fluency Test

*DLB-specific cognitive test battery designed to assess attention, executive function and visual learning
NTB composite: results of all six tests combined into single z-score
Attention composite: Detection and Identification tests combined into single z-score

AscenD-LB Clinical Trial Results

AscenD-LB

- Neflamapimod significantly (p=0.023) improved dementia severity (assessed by CDR-SB) compared to placebo and also showed significant (p=0.044) improvement on motor function (assessed by TUG test) compared to placebo
- Dose-response demonstrated, with neflamapimod also significantly (p=0.049) improving results on cognitive testing (assessed by NTB) at the higher dose level (40mg TID)
- Well tolerated, with no treatment discontinuations at 40mg TID dose level

Nature Communications, 13, Article number: 5308 (2022). https://www.nature.com/articles/s41467-022-32944-3

September 6th 2023 Press Release

CervoMed Announces Publication in the Journal *Neurology®* Results Showing a Blood Test at Study Entry Identified Patients Who Demonstrated Substantial Response to Neflamapimod Treatment in Dementia with Lewy Bodies

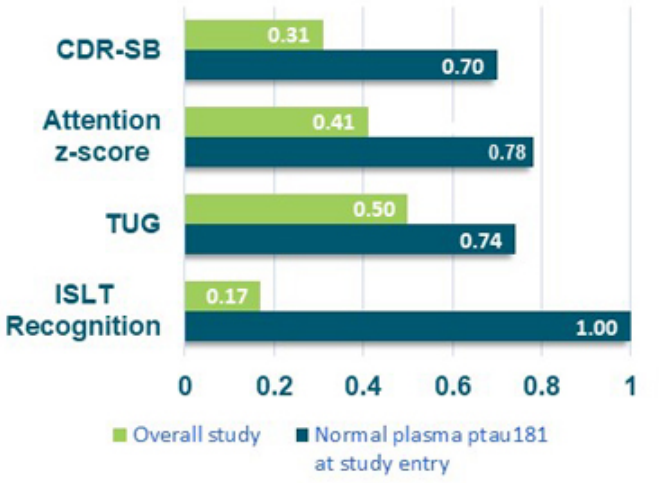
"The results support our long-standing thesis that the key to treating chronic neurodegenerative disease is to intervene early in the disease process, ahead of the patient having extensive neuronal loss in the brain"

"In the near term, we believe the exclusion of patients with abnormal levels of plasma ptau181 in our ongoing Phase 2b clinical trial of neflamapimod in patients with DLB will substantively increase the probability of success in that clinical trial."

Biomarker Results Support Enrichment Strategy for Phase 2b

- 35-50% of patients with DLB have biomarker evidence of Alzheimer's disease (AD) co-pathology
  - Represent patients with extensive neurodegeneration (nerve cell loss)
  - DLB patients without positive AD biomarkers have minimal neuronal loss, particularly in the hippocampus
- Blood-based biomarker, plasma ptau181, can detect AD co-pathology (Hall et al 2021)
- In phase 2a, plasma ptau181 identified the most responsive patients, with the magnitude of neflamapimod treatment effect being substantial in the 54% of patients with normal pre-treatment levels plasma ptau181

Cohen's d Effect Size at 40mg TID vs. Placebo



Alam et al, *Neurology*, Published online ahead of print, *September 1st 2023*

Phase 2b Confirmatory Study in DLB

CERVOMED

RewinD-LB

Patients

- DLB by consensus criteria (McKeith, *Neurology*, 2017)
- Abnormal dopamine uptake by DaTscan™
- Global CDR 0.5 or 1.0
- No AD co-pathology by plasma ptau181evaluation
- 160 patients (randomized 1:1 to placebo or NFMD)

16-WEEK TREATMENT, DOUBLE-BLIND
NFMD 40 mg TID or placebo, daily

32-WEEK TREATMENT, Open Label Extension
NFMD 40 TID

Outcome Measures

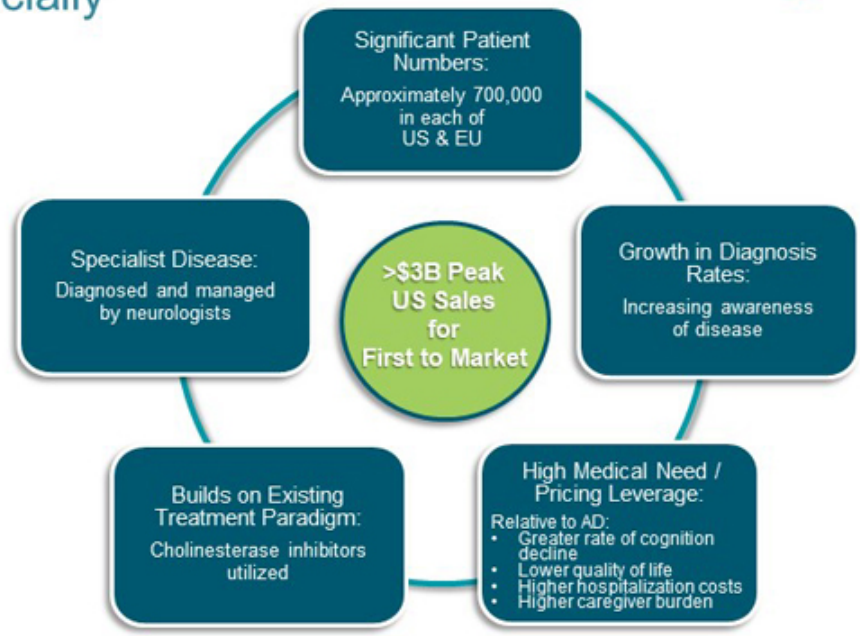
- 1º: CDR-Sum of Boxes
- 2º: Cognition assessed by DLB-specific Neuropsychological Test Battery (NTB), CGIC; Motor Function, assessed by Timed Up and Go (TUG) test

Other evaluations:

- **Fluctuation scale, NPI-12, MDS-UPDRS3**
- **EEG evaluations**
- **Structural MRI in 40 patients**

First patient dosed in August 2023; enrollment planned to be completed H1'24

Neflamapimod for DLB: Well-Positioned Commercially



Key Upcoming Anticipated Milestones/Catalysts

CERVOMED

1H 2023

- ✓ NIA approves $21M grant for Phase 2b
- ✓ Signed merger agreement with Diffusion Pharma
- ✓ Present data at AD/PD 2023
- ✓ Initiate Phase 2b DLB study

2H 2023

- ✓ FPD in Phase 2b DLB study
- ✓ Close merger transaction; begin trading as a public company
- ✓ Publish additional Phase 2a data[1] from DLB study in a major neurology journal
- ❑ Oral presentation at CTAD conference

2024

- ❑ Complete enrollment in Phase 2b DLB study (1H)
- ❑ Report data from placebo-controlled portion of Phase 2b DLB study (2H)

1. Plasma ptau181 stratified results.

Summary

- Differentiated Approach to Age-related Neurologic Disorders with a Late-Stage Asset
- Major value creation potential in phase 2b read-out in dementia with Lewy bodies
- Experienced Management Team and Board of Directors
- Potential to broaden opportunity through additional indications and 2nd asset
- Significant news flow through to end of 2024

CERVOMED

"Medicines for the Brain"

Corporate Overview

NASDAQ: CRVO

cerveau (sair-voh), noun, in French for *brain* or *mind*