# 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**

**May 15, 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**<br>**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 2.02 Results of Operations and Financial Condition**

*Earnings Press Release*

On May 15, 2024, CervoMed Inc. (the "Company," "we" or "us") issued a press release announcing financial results as of and for the quarter ended March 31, 2024. A copy of that press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information included in or incorporated by reference into this Item 2.02 (including Exhibit 99.1) is being furnished pursuant to Item 2.02 of Form 8-K and shall not be deemed to be "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 to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act.

**Item 9.01 Financial Statements and Exhibits**

***(d) Exhibits***

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press Release, issued May 15, 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: May 15, 2024

**CervoMed Inc.**
By: /s/ William Elder
Name: William Elder
Title: General Counsel

**CervoMed Reports First Quarter 2024 Financial Results and Provides Corporate Updates**

*- CervoMed on track to complete enrollment in 2Q 2024 in its RewinD-LB Phase 2b clinical trial evaluating neflamapimod in patients with dementia with Lewy bodies (DLB); topline data expected in 4Q 2024-*

*- Completed up to $149.4 million private placement with leading healthcare investors in early 2Q 2024 -*

**Boston – May 15, 2024** – CervoMed Inc. (NASDAQ: CRVO), a clinical stage company focused on developing treatments for age-related neurologic disorders, today reported its financial results for the first quarter ended March 31, 2024.

"Building on a year of high operational and clinical achievement, already in 2024, we have strengthened our financial resources and published data that further positions our lead clinical program, neflamapimod, as a highly differentiated, potential first-to-market treatment option for patients with DLB," said John Alam, MD, Chief Executive Officer of CervoMed. "In preclinical and clinical studies, neflamapimod has demonstrated the potential to modulate cholinergic dysfunction and degeneration, thereby reversing the underlying disease process in the basal forebrain and improving performance on cognitive and motor tasks. Our RewinD-LB Phase 2b clinical trial builds on these results, is well powered, designed to include DLB patients most likely to benefit from neflamapimod, and is expected to provide a path to market in this high value indication. We remain on track to complete enrollment in the RewinD-LB trial during the second quarter of this year, followed by topline efficacy results expected in the fourth quarter of 2024. In parallel, without distracting from our core focus on DLB, we also plan to explore opportunities to expand the therapeutic applications of neflamapimod to overcome existing challenges in additional cholinergic dysfunction driven neurological disorders."

**Recent Highlights and Anticipated Milestones**

- Enrollment in the randomized, controlled Phase 2b RewinD-LB clinical trial evaluating oral neflamapimod in patients with DLB continues to progress and CervoMed remains on track to complete enrollment in the second quarter of 2024.
    - During the first quarter of 2024, an integrated summary of results from the AscenD-LB Phase 2a clinical trial was published in a major peer-reviewed journal (Neurology®) and presentations at a major scientific conference (AD/PD™ 2024) further highlighted the potential of neflamapimod in "pure" DLB and the probability of success in RewinD-LB.

- On April 1, 2024, CervoMed completed a private placement of up to $149.4 million joined by leading healthcare investors. The gross upfront proceeds from the offering were approximately $50.0 million, with up to an additional $99.4 million if the warrants issued in connection with the offering are exercised in full. Cash and cash equivalents from the upfront proceeds of the offering, together with the CervoMed's cash and cash equivalents as of March 31, 2024, and remaining funds to be received from its NIA grant, are expected to provide runway through the end of 2025 based on CervoMed's current operating plan.

**First Quarter 2024 Financial Results**

**Cash Position:** As of March 31, 2024, CervoMed had approximately $6.4 million in cash and cash equivalents, as compared to approximately $7.8 million as of December 31, 2023. As CervoMed's private placement was completed and the upfront proceeds from the offering were received, in each case, on April 1, 2024, CervoMed's cash and cash equivalents balance as of March 31, 2024, does not include any proceeds from the offering.

**Grant Revenue:** In January 2023, CervoMed was awarded a $21.0 million grant from the National Institute on Aging to support the RewinD-LB Trial. Grant revenue was approximately $2.3 million for the three months ended March 31, 2024, compared to approximately $1.4 million for the same period in 2023.

**Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2024 were approximately $2.8 million, compared to approximately $1.8 million in the first quarter of 2023. This increase was primarily attributable to an increase in contract research organization and site expenses related to the RewinD-LB Trial.

**General and Administrative (G&A) Expenses:** G&A expenses were approximately $2.1 million during the first quarter of 2024 versus approximately $1.0 million in the first quarter of 2023. This increase was primarily attributable to increased accounting/audit fees, insurance costs, headcount costs, stock-based compensation expense due to additional stock options granted, and investor/public relations costs following the completion of CervoMed's reverse merger and commencement of trading as a public company in August 2023.

**Operating Loss:** Operating loss was approximately $2.6 million for the three months ended March 31, 2024, compared to approximately $1.4 million for the same period in 2023.

**Net Loss:** Net income was approximately $2.5 million for the three months ended March 31, 2024, compared to a net loss of approximately $0.5 million for the same period in 2023.

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

CervoMed's ongoing Phase 2b study, RewinD-LB, is a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID) in up to 160 patients with very mild or mild dementia due to DLB. Patients completing the 16-week placebo-controlled study period will be able to continue in the study while receiving open label neflamapimod treatment for an additional 32 weeks. Patients with Alzheimer's Disease-related co-pathology, assessed by a blood biomarker (plasma ptau181), will be excluded. The primary endpoint in the study is change in the Clinical Dementia Rating Sum of Boxes, and secondary endpoints include the Timed Up and Go test, a cognitive test battery, and the Clinician's Global Impression of Change. The RewinD-LB study is funded by a $21.0 million grant from the National Institutes of Health's National Institute on Aging, which will be disbursed over the course of the study as costs are incurred. The study includes 43 sites (32 in the United States, 8 in the United Kingdom, and 3 in the Netherlands), all of which have been initiated. More information on the RewinD-LB study, including contact information on active clinical trial sites, is available at clinicaltrials.gov.

**About CervoMed**
CervoMed Inc. (the "Company") 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 that inhibits p38MAP kinase alpha. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that causes disease in DLB and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with DLB.

**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, the anticipated timing and achievement of clinical and development milestones, including the completion and achievement of primary endpoints of the Company's Phase 2b clinical trial , the potential receipt of additional proceeds from the Company's private placement transaction completed in April 2024 upon the exercise of outstanding warrants, and the Company's projected cash runway. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential" 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 results of the Company's clinical trials; 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