# 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**

**August 12, 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**<br>**(Address of principal executive offices)** | **02116**<br>**(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**

On August 12, 2024, CervoMed Inc. (the "Company," "we" or "us") issued a press release announcing financial results as of and for the quarter ended June 30, 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 7.01 Regulation FD Disclosure**

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." 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 Securities and Exchange Commission ("SEC") and other public announcements that we 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 (including any information incorporated herein by reference) is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of Section 18 of the Exchange Act unless we specifically incorporate it by reference in a document filed under the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act or Exchange Act except as set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits**

***(d) Exhibits***

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, issued August 12, 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: August 15, 2024

**CervoMed Inc.**
By: /s/ William Elder
Name: William Elder
Title: Chief Financial Officer & General Counsel

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

*- Completed enrollment in its RewinD-LB Phase 2b clinical trial evaluating neflamapimod in patients with early-stage dementia with Lewy bodies (DLB) in June 2024; topline data expected in December 2024 -*

*- Hosted a virtual key opinion leader event in July 2024 highlighting neflamapimod's potential for patients with early-stage DLB –*

*- Completed private placement for up to $149.4 million of potential proceeds with leading institutional healthcare investors in April 2024 –*

*- Added to the Russell 2000® and Russell 3000® Indexes effective July 1, 2024, as part of the 2024 Russell U.S. Indexes annual reconstitution -*

**Boston – August 12, 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 second quarter ended June 30, 2024.

"In the second quarter, we continued to deliver on key milestones, highlighted by completing enrollment in RewinD-LB, our Phase 2b trial evaluating neflamapimod in patients with early-stage DLB, and we remain on track to report topline data from the study in December 2024," said John Alam, MD, Chief Executive Officer of CervoMed. "Approximately two-thirds of the paWents screened met the exclusion criteria for plasma ptau181—that is, they did not have advanced DLB—affirming our expectaWon that half or more of individuals with diagnosed DLB are sWll in the early stages of their disease. This, together with the high level of engagement across our clinical trial sites and the execution of our clinical team and partners, contributed to our ability to complete enrollment as planned. We look forward to building on the encouraging data from our Phase 2a AscenD-LB trial demonstraWng neflamapimod's potenWal to improve the lives of paWents by targeWng synapWc dysfuncWon in the basal forebrain cholinergic system to address cogniWve, funcWonal and motor aspects of the disease, and we believe a posiWve result in RewinD-LB will bring us one step closer to the market in this high value indicaWon. Beyond DLB, we conWnue to explore addiWonal opportuniWes to capitalize on neflamapimod's potenWal to overcome exisWng challenges in neurological disorders driven by cholinergic dysfuncWon. This includes progressing early-stage clinical acWviWes evaluaWng neflamapimod's potenWal to promote recovery from ischemic stroke and improve clinical outcomes in certain forms of frontotemporal demenWa."

**Recent Highlights and Anticipated Milestones**

- Completed enrollment in Phase 2b RewinD-LB clinical trial evaluating oral neflamapimod in patients with early-stage DLB in June 2024 and remain on track to report topline data from the study in December 2024.

- Hosted a virtual key opinion leader event on clinical disease expression of DLB, the role of the cholinergic system and neflamapimod's potential for patients with early-stage DLB in July 2024. The call featured presentations from John-Paul Taylor, MBBS (hons), MRCPsych, PhD (Newcastle University) and Ralph A. Nixon, MD, PhD (New York University Grossman School of Medicine). A replay is accessible on CervoMed's website.
- Completed a private placement for proceeds of up to $149.4 million with leading institutional healthcare investors in April 2024, with upfront gross proceeds of $50.0 million extending CervoMed's cash runway through 2025.
- On July 1, 2024, CervoMed was added to the Russell 2000® and Russell 3000® Indexes as part of the 2024 Russell U.S. Indexes annual reconstitution.

**Second Quarter 2024 Financial Results**

**Cash PosiCon:** As of June 30, 2024, CervoMed had approximately $50.9 million in cash, cash equivalents and marketable securiWes, as compared to approximately $7.8 million as of December 31, 2023. The increase in cash on-hand was primarily ajributable to the upfront proceeds received in CervoMed's private placement completed in April 2024. Based on its current operaWng plan, CervoMed believes its cash, cash equivalents and marketable securiWes on hand as of June 30, 2024, along with the remaining funds to be received from its NIA grant, will enable the company to fund its operaWng expenses and capital expenditure requirements through 2025.

**Grant Revenue:** In January 2023, CervoMed was awarded a $21.0 million grant from the NaWonal InsWtute on Aging to support the RewinD-LB Trial. Grant revenue was approximately $5.6 million for the six months ended June 30, 2024, compared to approximately $3.1 million for the same period in 2023. This increase was related to an increase in services performed during the six months ended June 30, 2024, as a result of, among other things, a larger number of trial sites being acWve during the current year period. CervoMed iniWated the RewinD-LB Trial in the second quarter of 2023 and completed enrollment in June 2024, with trial sites being acWvated on a rolling basis throughout the enrollment period.

**Research and Development (R&D) Expenses:** R&D expenses for the second quarter of 2024 were approximately $3.8 million, compared to approximately $2.0 million in the second quarter of 2023. This increase was primarily ajributable to an increase in outsourced contract research organizaWon costs and related site expenses related to the RewinD-LB Trial, services for which ramped up progressively between iniWaWon in the second quarter of 2023 and the compleWon of enrollment in June 2024.

**General and AdministraCve (G&A) Expenses:** G&A expenses were approximately $2.5 million during the second quarter of 2024 versus approximately $1.0 million in the second quarter of 2023. This increase was primarily ajributable to increased public company costs, including legal costs, insurance costs, headcount costs, stock-based compensaWon expense due to addiWonal stock opWons granted and an amendment to a former execuWve's previously granted opWon awards to extend the vesWng and exercise periods thereunder, and investor/public relaWons costs following the compleWon of CervoMed's reverse merger and commencement of trading as a public company in the third quarter of 2023.

**OperaCng Loss:** OperaWng loss was approximately $3.0 million for the three months ended June 30, 2024, compared to approximately $1.2 million for the same period in 2023.

**Net Loss:** Net loss was approximately $2.3 million for the three months ended June 30, 2024, compared to a net loss of approximately $1.4 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, placebocontrolled clinical trial evaluating oral neflamapimod (40mg TID) in 159 patients with early-stage DLB. In early-stage DLB patients – who are estimated to comprise approximately 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 significant, irreversible neuronal loss in the hippocampus and associated Alzheimer's Disease co-pathology -- as assessed by a blood biomarker (plasma ptau181), were excluded from the study. 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 is being 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) and completed enrollment in June 2024, with topline data expected in December 2024. 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. 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 agerelated neurologic disorders. The Company is currently developing neflamapimod, an investigational, orally administered small molecule brain penetrant that inhibits 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 DLB and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with early-stage 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 Company's financial position and cash runway, the therapeutic potential of neflamapimod, and the anticipated timing and achievement of clinical and development milestones, including the completion and achievement of primary endpoints of the RewinD-LB Phase 2b clinical trial and the Company's announcement of topline data therefrom. 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 forwardlooking 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:**
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**CervoMed Inc.**
**Condensed Consolidated Balance Sheets**
**(unaudited)**

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,009,217 | $ 7,792,846 |
| Marketable securities, current | 35,082,502 | — |
| Prepaid expenses and other current assets | 2,236,436 | 1,256,501 |
| Grant receivable | — | 915,404 |
| Total current assets | 47,328,155 | 9,964,751 |
| Marketable securities, non-current | 5,806,260 | — |
| Other assets | 56,234 | 7,770 |
| Total assets | $ 53,190,649 | $ 9,972,521 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 725,854 | $ 662,471 |
| Deferred grant revenue | 1,401,501 | — |
| Accrued expenses and other current liabilities | 1,086,381 | 1,933,276 |
| Total liabilities | 3,213,736 | 2,595,747 |
| Commitments and Contingencies (Note 9) | | |
| Stockholders' Equity: | | |
| Common stock, $0.001 par value: 1,000,000,000 shares authorized: 8,253,741 and 5,674,520 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 8,253 | 5,674 |
| Additional paid-in capital | 109,260,391 | 61,811,889 |
| Accumulated other comprehensive loss | (19,702) | — |
| Accumulated deficit | (59,272,029) | (54,440,789) |
| Total stockholders' equity | 49,976,913 | 7,376,774 |
| Total liabilities and stockholders' equity | $ 53,190,649 | $ 9,972,521 |

**CervoMed Inc.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2024 | 2023 (As Restated) | 2024 | 2023 (As Restated) |
| Grant revenue | $ 3,288,971 | $ 1,719,944 | $ 5,636,221 | $ 3,127,812 |
| Operating expenses: | | | | |
| Research and development | 3,772,391 | 1,958,388 | 6,586,649 | 3,791,662 |
| General and administrative | 2,511,679 | 992,553 | 4,639,609 | 1,993,466 |
| Total operating expenses | 6,284,070 | 2,950,941 | 11,226,258 | 5,785,128 |
| Loss from operations | (2,995,099) | (1,230,997) | (5,590,037) | (2,657,316) |
| Other income (expense): | | | | |
| Other income (expense) | (247) | (212,211) | (277) | 644,368 |
| Interest income | 678,441 | 17,707 | 759,074 | 53,111 |
| Total other income, net | 678,194 | (194,504) | 758,797 | 697,479 |
| Net loss | $ (2,316,905) | $ (1,425,501) | $ (4,831,240) | $ (1,959,837) |
| Per share information: | | | | |
| Net loss per share of common stock, basic and diluted | $ (0.27) | $ (2.75) | $ (0.65) | $ (3.78) |
| Weighted average shares outstanding, basic and diluted | 8,702,764 | 518,140 | 7,436,633 | 518,140 |
| Comprehensive loss: | | | | |
| Net unrealized loss on marketable securities | (19,702) | — | (19,702) | — |
| Total comprehensive loss | $ (2,336,607) | $ (1,425,501) | $ (4,850,942) | $ (1,959,837) |