



CervoMed Reports First Quarter 2025 Financial Results and Provides Corporate Updates

May 12, 2025

Reported positive 16-week results from the extension phase of the Phase 2b RewinD-LB trial, demonstrating proof-of-concept for neflamapimod as a potential treatment for dementia with Lewy bodies (DLB)

Plan to initiate Phase 3 trial of neflamapimod in DLB in mid-2026 following meeting with regulatory authorities

Initiating separate Phase 2a trials to evaluate neflamapimod in patients with primary progressive aphasia and patients in the recovery phase after ischemic stroke

BOSTON, May 12, 2025 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO), a clinical stage company focused on developing treatments for age-related neurologic disorders (CervoMed or the Company), today reported its financial results for the first quarter ended March 31, 2025.

"The first quarter of 2025 represented a tidal shift for CervoMed. We believe the evidence of slowed clinical progression demonstrated in the 16-week results from the extension phase of our RewinD-LB trial affirm our initial hypothesis of drug benefit, and explain the results from the initial phase of the trial reported in December 2024. More importantly, we believe the 16-week data demonstrate proof-of-concept for neflamapimod as a potential treatment for DLB, underscoring neflamapimod's first-to-market potential for this devastating disease. We anticipate 32-week results from the extension phase in the second half of 2025 and are actively preparing for discussions with the U.S. Food and Drug Administration (FDA) regarding the design of our Phase 3 trial, which we plan to initiate in mid-2026," said John Alam, MD, Chief Executive Officer of CervoMed. "In parallel, in the near future we will be initiating a Phase 2 trial evaluating neflamapimod in patients with primary progressive aphasia (PPA), and recently initiated a Phase 2 trial in patients recovering from ischemic stroke—important steps that we believe complement our lead DLB program, build on the compelling data seen so far, and expand our exploration of neflamapimod's full therapeutic potential. I want to express my deep gratitude to our dedicated scientific team, as well as to the patients and caregivers participating in our clinical programs."

Recent Highlights and Anticipated Milestones

- In March 2025, CervoMed reported positive 16-week results from the extension phase of the RewinD-LB trial in which patients who were administered a more recently manufactured batch of neflamapimod capsules had higher plasma drug concentration levels and demonstrated improvements on the primary outcome measure, Clinical Dementia Rating Sum of Boxes (CDR-SB) ($p < 0.001$ v. old capsules; $p = 0.003$ v. placebo), and a key secondary endpoint. The full details on these results can be found [here](#).
- In April 2025, the full 16-week results from the extension phase of the Phase 2b RewinD-LB trial demonstrating a meaningful beneficial impact on clinical progression in patients treated with neflamapimod compared to controls were presented at the 19th International Conference on Alzheimer's and Parkinson's Diseases and Related Neurologic Disorders (AD/PD™) in Vienna, Austria. The full details of these results can be found [here](#).
- The Company expects to report 32-week results from the extension phase of the RewinD-LB trial in the second half of 2025.
- Initial safety, biomarker and pharmacokinetic data from an ongoing trial in patients with mild-to-moderate DLB evaluating a twice daily regimen (80mg BID) of neflamapimod are expected to be available in the fourth quarter of 2025.
- The Company plans to initiate a Phase 3 trial in DLB in mid-2026, following a meeting with the FDA and subject to available funding.
- CervoMed recently initiated a Phase 2a trial evaluating neflamapimod in patients recovering from ischemic stroke and plans to initiate a Phase 2a trial in patients with the nonfluent/agrammatic variant of PPA – a subtype of frontotemporal dementia (FTD) – in mid-2025. In November 2024, the FDA granted neflamapimod Orphan Drug designation for the treatment of FTD.

First Quarter 2025 Financial Results

Cash Position: As of March 31, 2025, CervoMed had approximately \$35.2 million in cash, cash equivalents and marketable securities, as compared to \$38.9 million as of December 31, 2024. Based on its current operating plan, CervoMed believes its cash, cash equivalents and marketable securities on hand as of March 31, 2025, along with the remaining funds to be received from the Company's grant from the National Institutes of Health's National Institute on Aging (NIA), will enable the Company to fund its planned operating expenses and capital expenditure requirements into mid-2026.

Grant Revenue: In January 2023, CervoMed was awarded a \$21.0 million grant from the NIA to support the RewinD-LB trial and, in August 2024, CervoMed was awarded an additional \$0.3 million under the grant. Grant revenue was approximately \$1.9 million for the three months ended March 31, 2025, compared to approximately \$2.3 million for the same period in 2024. This decrease was related to a decrease in services performed with respect to the RewinD-LB trial during the three months ended March 31, 2025, as a result of, among other things, the trial transitioning from the double-blind initial phase to the ongoing extension phase.

Research and Development (R&D) Expenses: R&D expenses for the three months ended March 31, 2025, were approximately \$4.8 million, compared to approximately \$2.8 million in 2024. This increase was attributable to chemistry, manufacturing and controls activities, increased non-clinical studies, increased headcount costs, and outsourced contract research organization costs related to clinical work for neflamapimod, including start-up costs related to our recently initiated Phase 2a clinical trial in recovery after ischemic stroke and our planned Phase 2a clinical trial in PPA, which we intend to initiate in mid-2025.

General and Administrative (G&A) Expenses: G&A expenses were approximately \$2.4 million during the three months ended March 31, 2025, versus approximately \$2.1 million in the same period in 2024. The increase was primarily due to increased headcount costs and

outsourced services.

Net Loss: Net loss was approximately \$4.9 million for the three months ended March 31, 2025, compared to net loss of approximately \$2.5 million for the same period in 2024.

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

The initial phase of RewinD-LB is a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID), with a 32-week neflamapimod only treatment Extension phase in 159 patients with DLB. Patients with AD co-pathology, as assessed by plasma ptau181 levels, were excluded from the trial. Compared to patients with “pure” DLB – who may comprise up to 50% of the total diagnosed DLB patient population at any given time – DLB patients with Alzheimer’s disease co-pathology have significant, irreversible neuronal loss in the hippocampus that limits response to treatment. The primary outcome measure in the trial is change in CDR-SB, and secondary endpoints include Alzheimer’s Disease Cooperative Study - Clinical Global Impression of Change, the Timed Up and Go test, and a cognitive test battery. The RewinD-LB trial is funded primarily by a \$21.3 million grant from the NIA, which is expected to be disbursed over the course of the trial as costs are incurred. The trial includes 43 sites across in the United States, the United Kingdom, and the Netherlands. Participants completing the 16-week initial phase of the trial were able to continue in the trial while receiving neflamapimod treatment for an additional 32-week extension phase, within which the same efficacy assessments were conducted during the first 16 weeks as were obtained during the Initial phase.

About CervoMed

CervoMed 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 p38 mitogen-activated protein kinase alpha. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause 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 Company’s financial position and cash runway, the therapeutic potential of neflamapimod, the anticipated timing and achievement of clinical and development milestones, including the completion the RewinD-LB Phase 2b clinical trial and the Company’s announcement of additional data therefrom, 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 timing of the initiation of any potential future trials or interactions with regulatory authorities, including the Company’s need to acquire sufficient funding prior to initiating any Phase 3 trial of neflamapimod in DLB. 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 FDA; 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, 2024 filed with the U.S. Securities and Exchange Commission (SEC) on March 17, 2025, 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

CervoMed Inc. Condensed Consolidated Balance Sheets

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,501,714	\$ 8,999,496
Marketable securities	24,742,800	29,922,523
Prepaid expenses and other current assets	1,703,747	1,905,360
Grant receivable	1,629,227	2,254,231
Total current assets	<u>38,577,488</u>	<u>43,081,610</u>
Total assets	<u>\$ 38,577,488</u>	<u>\$ 43,081,610</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,860,598	1,511,440
Accrued expenses and other current liabilities	<u>2,082,403</u>	<u>2,367,842</u>
Total liabilities	3,943,001	3,879,282
Commitments and Contingencies (Note 8)		
Stockholders' Equity:		

Series A preferred stock \$0.001 par value; 30,000,000 authorized at March 31, 2025 and December 31, 2024, 0 shares issued and outstanding at March 31, 2025 and December 31, 2024

Common stock, \$0.001 par value: 1,000,000,000 shares authorized: 8,702,719 shares issued and outstanding at March 31, 2025 and December 31, 2024

	-	-
	8,702	8,702
Additional paid-in capital	110,230,080	109,868,913
Accumulated other comprehensive income	21,223	56,197
Accumulated deficit	<u>(75,625,518)</u>	<u>(70,731,484)</u>
Total stockholders' equity	<u>34,634,487</u>	<u>39,202,328</u>
Total liabilities and stockholders' equity	<u>\$ 38,577,488</u>	<u>\$ 43,081,610</u>

CervoMed Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended March 31,	
	2025	2024
Grant revenue	\$ 1,917,491	\$ 2,347,250
Operating expenses:		
Research and development	4,837,798	2,814,258
General and administrative	<u>2,382,577</u>	<u>2,127,930</u>
Total operating expenses	<u>7,220,375</u>	<u>4,942,188</u>
Loss from operations	(5,302,884)	(2,594,938)
Other income (expense):		
Other expense	(135)	(30)
Interest income	<u>408,985</u>	<u>80,633</u>
Total other income, net	<u>408,850</u>	<u>80,603</u>
Net loss	<u>\$ (4,894,034)</u>	<u>\$ (2,514,335)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.41)</u>
Weighted average shares outstanding, basic and diluted	<u>8,702,719</u>	<u>6,170,501</u>
Comprehensive loss:		
Net unrealized loss on marketable securities	<u>(34,974)</u>	<u>-</u>
Total comprehensive loss	<u>\$ (4,929,008)</u>	<u>\$ (2,514,335)</u>



Source: CervoMed Inc.