CervoMed Reports Second Quarter 2025 Financial Results and Provides Corporate Updates

August 11, 2025

Reported 32-week data from Phase 2b RewinD-LB Trial Extension phase showing neflamapimod treatment resulted in a substantial reduction in clinically significant worsening compared to control arm over 32 weeks, which improved further among patients who have minimal evidence of Alzheimer's disease (AD) co-pathology (ptau181 < 2.2 pg/mL at screening)

At week 32 of the Extension phase, patients treated with neflamapimod demonstrated a significant reduction from baseline in plasma levels of glial fibrillary acidic protein (GFAP)

Plan to engage with U.S. Food and Drug Administration (FDA) in the fourth quarter of 2025 to align on trial design for the Phase 3 program in Dementia with Lewy Bodies (DLB)

BOSTON, Aug. 11, 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 and corporate updates for the second quarter ended June 30, 2025.

"With the reporting of both 16- and 32-week Extension phase data from the Phase 2b RewinD-LB trial, we have solidified the evidence for slowing clinical progression in DLB associated with neflamapimod treatment. This proof-of-concept, combined with the notable reductions seen in plasma levels of GFAP, an important blood-based biomarker of the underlying neurodegenerative process in DLB, provide us with valuable results and a deeper understanding that further increases our confidence in Phase 3 success and neflamapimod's potential to make a meaningful difference for patients if approved. We are actively preparing for discussions with the FDA, which we expect to take place in the fourth quarter of 2025, to align on the design of our planned Phase 3 trial," said John Alam, MD, Chief Executive Officer of CervoMed.

Recent Highlights and Anticipated Milestones

- In July 2025, the Company presented 32-week results from the open-label Extension phase of the Phase 2b RewinD-LB trial at the Alzheimer's Association International Conference in Toronto, Canada. Based on the primary endpoint of Clinical Dementia Rating Sum of Boxes (CDR-SB), patients treated with neflamapimod showed 54% risk reduction in clinically significant worsening compared to control at Week 32 of treatment (p=0.0037). This risk reduction improved to 64% (p=0.0001) among patients who have minimal evidence of AD co-pathology (ptau181 < 2.2 pg/mL at screening).
- In July 2025, the Company also announced that at Week 32 of the Phase 2b RewinD-LB Extension phase, there was a statistically significant reduction (p<0.0001) from baseline (i.e., start of Extension) in GFAP plasma levels in patients who received active neflamapimod for all 32 weeks, with a mean change of -18.4±4.0 pg/mL in all participants (N=107) and -21.2±4.4 pg/mL in participants with screening plasma ptau181 below 2.2 pg/mL (N=91). In contrast, placebo-recipients in the initial, double-blind phase of the trial had a mean increase from baseline to Week 16 of +1.1±3.0 pg/mL in all participants (N=74) and +1.1±3.3 pg/mL in the subset with screening plasma ptau181 below 2.2 pg/mL (N=65). The full details of these results can be found here.
- In June 2025, the Company announced that Marco Verwijs, PhD joined CervoMed as Executive Vice President, Technical Operations, a key senior leadership role to oversee the Company's Chemistry, Manufacturing, and Controls (CMC) division and advance the development of neflamapimod through Phase 3 testing and preparation of commercial batches.
- 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 plans to meet with the FDA in the fourth quarter of 2025 to align on the design of the Company's planned Phase 3 trial, which it plans to initiate in mid-2026 subject to available funding.
- 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.
- In the second of quarter of 2025, CervoMed enrolled the first patients in a Phase 2a trial of neflamapimod in patients recovering from acute stroke and initiated a Phase 2a trial of neflamapimod in patients with the nonfluent/agrammatic variant of primary progressive aphasia (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.

Second Quarter 2025 Financial Results

Cash Position: As of June 30, 2025, CervoMed had approximately $33.5 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 June 30, 2025, along with remaining funds to be received from the Company's grant from the NIA, will enable the Company to fund its planned operating expenses and capital expenditure requirements into the third quarter of 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 $1.8 million for the three months ended June 30, 2025, compared to approximately $3.3 million for the same period in 2024. The decrease is due to the completion of the initial, double-blind phase of the RewinD-LB Trial and transition to the Extension phase in December 2024.

Research and Development (R&D) Expenses: R&D expenses for the quarter ended June 30, 2025, were approximately $5.1 million, compared to approximately $3.8 million in the same period in 2024. The increase of $1.3 million was primarily due to an increase in costs related to CMC activities,

increased non-clinical studies, increased headcount costs, and outsourced CRO costs related to clinical work for neflamapimod, including costs related to our Phase 2a clinical trials of neflamapimod in recovery from acute stroke and with the nonfluent/agrammatic variant of PPA, both of which were initiated in the second quarter of 2025.

General and Administrative (G&A) Expenses: G&A expenses were approximately $3.3 million during the three months ended June 30, 2025, versus approximately $2.5 million in the same period in 2024. The increase of $0.8 million was primarily due to headcount costs and outsourced services.

Net Loss: Net loss was approximately $6.3 million for the three months ended June 30, 2025, compared to net loss of approximately $2.3 million for the same period in 2024.

About the RewinD-LB Phase 2b Trial in Dementia with Lewy Bodies
The initial phase of RewinD-LB was a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID) in 159 patients with DLB, followed by a 32-week neflamapimod-only treatment Extension phase. 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 AD co-pathology have significant, irreversible neuronal loss in the hippocampus that limits response to treatment. The primary endpoint in the trial is change in the CDR-SB, and secondary endpoints include the 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 National Institutes of Health's National Institute on Aging, 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. The initial phase of the study did not effectively evaluate the clinical activity of 40mg TID neflamapimod compared to placebo because the batch of neflamapimod capsules utilized during the placebo-controlled phase of the study did not lead to the plasma drug concentrations expected with such a dose. However, in the Extension phase, a portion of patients were administered a more recently manufactured batch of capsules that achieved targeted plasma drug concentrations, allowing the effects of 40 mg TID neflamapimod treatment to be effectively evaluated during the Extension phase, with patients receiving the newer capsules serving as an active drug arm. Outcomes in these patients were compared with those in the subset of patients who continued to receive the older batch of capsules during the Extension phase, which served as a control arm.

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. Our recently completed Phase 2b trial evaluated neflamapimod 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 cash runway; the therapeutic potential of neflamapimod, including the degree of sustainability of any therapeutic effects; the anticipated timing and achievement of clinical and development milestones, including the Company's announcement of additional data, if any, from the RewinD-LB Phase 2b clinical trial and any meeting or correspondence between the Company and the FDA; any other expected or implied benefits or results, including that any initial clinical results observed with respect to neflamapimod in the 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 for 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.

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CervoMed Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 8,320,713	$ 8,999,496
Marketable securities	25,210,453	29,922,523
Prepaid expenses and other current assets	1,964,327	1,905,360
Deferred offering costs	224,931	—
Grant receivable	2,360,975	2,254,231
Total current assets	38,081,399	43,081,610
Total assets	$ 38,081,399	$ 43,081,610

Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,845,609	$ 1,511,440
Accrued expenses and other current liabilities	2,796,011	2,367,842
Total liabilities	4,641,620	3,879,282
Commitments and Contingencies (Note 8)		
Stockholders' Equity:		
Series A preferred stock $0.001 par value: 30,000,000 authorized at June 30, 2025 and December 31, 2024, 0 shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value: 1,000,000,000 shares authorized at June 30, 2025 and December 31, 2024: 9,252,719 and 8,702,719 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	9,252	8,702
Additional paid-in capital	115,315,232	109,868,913
Accumulated other comprehensive (loss) income	(783)	56,197
Accumulated deficit	(81,883,922)	(70,731,484)
Total stockholders' equity	33,439,779	39,202,328
Total liabilities and stockholders' equity	$ 38,081,399	$ 43,081,610

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Grant revenue	$ 1,757,724	$ 3,288,971	$ 3,675,215	$ 5,636,221
Operating expenses:				
Research and development	5,108,625	3,772,391	9,946,423	6,586,649
General and administrative	3,265,374	2,511,679	5,647,951	4,639,609
Total operating expenses	8,373,999	6,284,070	15,594,374	11,226,258
Loss from operations	(6,616,275)	(2,995,099)	(11,919,159)	(5,590,037)
Other income (expense):				
Other expense	(10,256)	(247)	(10,391)	(277)
Interest income	368,127	678,441	777,112	759,074
Total other income, net	357,871	678,194	766,721	758,797
Net loss	$ (6,258,404)	$ (2,316,905)	$ (11,152,438)	$ (4,831,240)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.70)	$ (0.27)	$ (1.26)	$ (0.65)
Weighted average shares outstanding, basic and diluted	8,950,521	8,702,764	8,827,305	7,436,633
Net loss:				
Net unrealized loss on marketable securities	(22,006)	(19,702)	(56,980)	(19,702)
Total comprehensive loss	$ (6,280,410)	$ (2,336,607)	$ (11,209,418)	$ (4,850,942)

Source: CervoMed Inc.