CervoMed Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Updates

March 17, 2025

-Reported positive 16-week results from the extension phase of the Phase 2b RewinD-LB trial of neflamapimod in dementia with Lewy bodies (DLB), including improvement on the trial's primary outcome measure-

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

-Awarded 2024 Prix Galien USA Award as "Best Startup" by the Galien Foundation-

BOSTON, March 17, 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 fourth quarter and full year ended December 31, 2024.

"Following the highly encouraging 16-week extension results from our Phase 2b RewinD-LB trial, we believe we have established proof-of-concept for neflamapimod as a potential treatment for DLB. Our team is now focused on reporting the results from the 32-week extension phase in the second half of 2025 and discussing next steps on Phase 3 trial design with regulatory authorities," said John Alam, MD, Chief Executive Officer of CervoMed.

Recent Highlights and Anticipated Milestones

- The 16-week results from the extension phase of the Phase 2b RewinD-LB trial have been accepted as an oral presentation at the 19th International Conference on Alzheimer's and Parkinson's Diseases and Related Neurologic Disorders (AD/PD™) in Vienna, Austria, April 1-5, 2025.
- 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 new batch of neflamapimod capsules had higher plasma drug concentration levels and demonstrated improvements on the primary outcome measure, Clinical Dementia Rating Sum of Boxes ($p<0.001$ v. old capsules; $p=0.003$ v. placebo), and a key secondary endpoint. The full details on these results can be found here.
    - 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 being treated with a twice daily regimen (80mg BID) of neflamapimod is expected to be available in the fourth quarter of 2025.
- In January 2025, the Company presented at the 8th International Lewy Body Dementia Conference (ILBDC) in Amsterdam, the Netherlands.
- During 2025, CervoMed plans to also advance neflamapimod development in additional diseases:
    - In November 2024, the U.S. Food and Drug Administration (FDA) granted neflamapimod Orphan Drug designation for the treatment of frontotemporal dementia (FTD) and CervoMed plans to initiate a Phase 2a trial evaluating neflamapimod in the nonfluent/agrammatic variant of primary progressive aphasia – a subtype of FTD – in mid-2025.
    - In the second quarter of 2025, CervoMed plans to initiate the Phase 2 Restore Trial to evaluate neflamapimod in patients recovering from ischemic stroke.
- Fourth Quarter 2024 Highlights:
    - CervoMed added to its leadership team with the appointments of Claudia Ordonez, MD, as Senior Vice President, Medical Science, and Mark De Rosch, Ph.D., FRAPS, as Senior Vice President, Regulatory and Government Affairs and Program Management.
    - CervoMed was awarded the 2024 Prix Galien USA 2024 prize in the "Best Startup" category by the Galien Foundation, a premier global institution dedicated to honoring innovators in life sciences.

Full Year 2024 Financial Results

Cash Position: As of December 31, 2024, CervoMed had approximately $38.9 million in cash, cash equivalents and marketable securities, as compared to $7.8 million as of December 31, 2023. The increase in cash on-hand compared to 2023 was primarily attributable to the upfront proceeds received in CervoMed's private placement completed in April 2024. Based on its current operating plan, CervoMed believes its cash, cash equivalents and marketable securities on hand as of December 31, 2024, 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 National Institute on Aging of the National Institutes of Health (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 $9.7 million for the twelve months ended December 31, 2024, compared to approximately $7.1 million for the same period in 2023. This increase was related to an increase in services performed during the twelve months ended December 31, 2024, as a result of, among other things, a larger number of trial sites being active in the RewinD-LB trial during 2024.

Research and Development (R&D) Expenses: R&D expenses for the twelve months ended December 31, 2024, were approximately $18.8 million, compared to approximately $8.4 million in 2023. This increase was primarily attributable to an increase in outsourced contract research organization costs and related site expenses related to the RewinD-LB trial, services for which ramped up progressively between initiation in the third quarter of 2023 and the completion of enrollment in June 2024.

General and Administrative (G&A) Expenses: G&A expenses were approximately $9.2 million during the twelve months ended December 31, 2024, versus approximately $6.5 million in the same period in 2023. The increases were primarily due to outsourced legal costs, insurance costs, headcount costs, investor/public relations costs, and stock-based compensation expense as a result of, among things, increased headcount and a full-year of public company expenses in the current year period.

Operating Loss: Operating loss was approximately $18.2 million for the twelve months ended December 31, 2024, compared to approximately $7.8 million for the same period in 2023.

Net Loss: Net loss was approximately $16.3 million for the twelve months ended December 31, 2024, compared to net loss of approximately $2.2 million for the same period in 2023. The lower net loss in 2023 was driven by a noncash gain recognized for the conversion of the convertible notes upon the closing of the Company's reverse merger, which was based on the stock price on the date of the transaction.

About the RewinD-LB Phase 2b Trial 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) in 159 patients with DLB. Patients with Alzheimer's disease (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. The primary endpoint in the trial is change in the Clinical Dementia Rating Sum of Boxes, 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, which includes a pre-specified data readout after the first 16 weeks.

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 causes disease in DLB and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b trial 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.

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CervoMed Inc.
Condensed Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 8,999,496	$ 7,792,846
Marketable securities	29,922,523	—
Prepaid expenses and other current assets	1,905,360	1,256,501
Grant receivable	2,254,231	915,404
Total current assets	43,081,610	9,964,751
Other assets	—	7,770
Total assets	$ 43,081,610	$ 9,972,521
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,511,440	$ 662,471
Accrued expenses and other current liabilities	2,367,842	1,933,276
Total liabilities	3,879,282	2,595,747
Commitments and Contingencies (Note 10)		

Stockholders' Equity:		
Series A preferred stock $0.001 par value; 30,000,000 authorized at December 31, 2024 and December 31, 2023, 0 shares issued and outstanding at December 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value: 1,000,000,000 shares authorized: 8,702,719 and 5,674,520 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	8,702	5,674
Additional paid-in capital	109,868,913	61,811,889
Accumulated other comprehensive income	56,197	—
Accumulated deficit	(70,731,484)	(54,440,789)
Total stockholders' equity	39,202,328	7,376,774
Total liabilities and stockholders' equity	$ 43,081,610	$ 9,972,521

CervoMed Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2024	**2023**
Grant revenue	$ 9,737,974	$ 7,144,872
Operating expenses:		
Research and development	18,798,343	8,438,499
General and administrative	9,166,762	6,519,268
Total operating expenses	27,965,105	14,957,767
Loss from operations	(18,227,131)	(7,812,895)
Other income:		
Other income (expense)	(991)	5,421,592
Interest income	1,937,427	219,430
Total other income, net	1,936,436	5,641,022
Net loss	$ (16,290,695)	$ (2,171,873)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (2.02)	$ (0.82)
Weighted average shares outstanding, basic and diluted	8,073,155	2,661,416
Comprehensive loss:		
Net unrealized gain on marketable securities	56,197	—
Total comprehensive loss	$ (16,234,498)	$ (2,171,873)

Source: CervoMed Inc.