CervoMed Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

November 12, 2024

- Reported last patient, last visit in its RewinD-LB Phase 2b clinical trial evaluating neflamapimod in patients with early-stage dementia with Lewy bodies (DLB) in October 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 –

BOSTON, Nov. 12, 2024 (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 third quarter ended September 30, 2024.

"In the third quarter, we conducted the final patient visits in RewindD-LB, our Phase 2b trial evaluating neflamapimod in patients with early-stage DLB and began to prepare for database lock in the fourth quarter. We remain on track to report topline data from the study in December 2024," said John Alam, MD, Chief Executive Officer of CervoMed. "Additionally, we carried out important chemistry, manufacturing and controls (CMC) activities to prepare for Phase 3 trial initiation in mid-2025 after a planned end-of-Phase 2 meeting with the FDA. While our core focus remains on the opportunity in DLB, we also plan to initiate a Phase 2a trial to evaluate neflamapimod's potential to promote recovery from ischemic stroke in the first quarter of 2025, for which we recently obtained ethics committee approval."

Recent Highlights and Anticipated Milestones

- In November 2024, CervoMed was selected as "Best Startup" in the 2024 Prix Galien USA Award by the Galien Foundation, a premier global institution dedicated to honoring innovators in life sciences.
- Delivered two oral presentations at the recent Clinical Trials on Alzheimer's Disease Conference (CTAD) showing neflamapimod demonstrated a treatment effect on plasma glial fibrillary acid protein, a robust measure of neurogenerative disease activity in DLB, and that the RewinD-LB study enrolled a population that is optimized to show the treatment effect. Full details on the CTAD presentation can be found here.
- Reported last patient, last visit had occurred in the Phase 2b RewinD-LB clinical trial evaluating oral neflamapimod in patients with early-stage DLB in October 2024 and remain on track to report topline data from the study in December 2024.
- Plasma biomarker data from the AscenD-LB Phase 2a trial of neflamapimod in patients with DLB were featured in a poster presentation at the Alzheimer's Association International Conference®, held in Philadelphia on July 29, 2024. A PDF copy of the poster presentation is available on the "Presentations and Publications" section of the CervoMed website.
- 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.
- 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.

Third Quarter 2024 Financial Results

Cash Position: As of September 30, 2024, CervoMed had approximately $46.7 million in cash, cash equivalents and marketable securities, as compared to approximately $50.9 million and $7.8 million as of June 30, 2024, and December 31, 2023, respectively. The increase in cash on-hand compared to year-end 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 September 30, 2024, along with the remaining funds to be received from its National Institute on Aging of the National Institutes of Health (NIA) grant, will enable the Company to fund its operating expenses and capital expenditure requirements through 2025.

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 September 30, 2024, compared to approximately $1.5 million for the same period in 2023. This increase was related to an increase in services performed during the nine months ended September 30, 2024, as a result of, among other things, a larger number of trial sites being active in the RewinD-LB trial during the current year period.

Research and Development (R&D) Expenses: R&D expenses for the three months ended September 30, 2024, were approximately $5.1 million, compared to approximately $1.8 million in the same period 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 $2.2 million during the three months ended September 30, 2024, versus approximately $2.4 million in the same period in 2023. The slight decrease of $0.2 million was primarily due to fewer one-time professional fee costs incurred related to the Company's reverse merger in August 2023, including D&O insurance, public relations, and accounting services.

Operating Loss: Operating loss was approximately $5.4 million for the three months ended September 30, 2024, compared to approximately $2.7 million for the same period in 2023.

Net Loss: Net loss was approximately $4.8 million for the three months ended September 30, 2024, compared to net income of approximately $2.2 million for the same period in 2023. The net income in the prior year period was driven primarily by a non-cash fair value adjustment to previously outstanding convertible notes, which converted into shares of CervoMed common stock in connection with the reverse merger in August 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 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 $21.3 million grant from the NIA, which is being disbursed over the course of the study as costs are incurred. The study includes 43 sites (32 in the United States, eight in the United Kingdom, and three 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 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 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, 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 and other data therefrom, and 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, as well as the timing of the initiation of any potential future trials. 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 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.

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CervoMed Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 7,743,667	$ 7,792,846
Marketable securities, current	38,913,236	—
Prepaid expenses and other current assets	1,888,879	1,256,501
Grant receivable	264,148	915,404
Total current assets	48,809,930	9,964,751
Other assets	73,937	7,770
Total assets	$ 48,883,867	$ 9,972,521
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,082,435	$ 662,471
Accrued expenses and other current liabilities	2,163,936	1,933,276
Total liabilities	3,246,371	2,595,747
Commitments and Contingencies (Note 10)		
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 September 30, 2024 and December 31, 2023, respectively	8,253	5,674
Additional paid-in capital	109,531,651	61,811,889
Accumulated other comprehensive income	123,162	—
Accumulated deficit	(64,025,570)	(54,440,789)

Total stockholders' equity	45,637,496	7,376,774
Total liabilities and stockholders' equity	$ 48,883,867	$ 9,972,521

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Grant revenue	$ 1,939,751	$ 1,526,482	$ 7,575,972	$ 4,654,294
Operating expenses:				
Research and development	5,125,097	1,791,487	11,711,746	5,583,149
General and administrative	2,210,927	2,410,124	6,850,536	4,403,590
Total operating expenses	7,336,024	4,201,611	18,562,282	9,986,739
Loss from operations	(5,396,273)	(2,675,129)	(10,986,310)	(5,332,445)
Other income (expense):				
Other income (expense)	(3,440)	4,777,824	(3,717)	5,422,192
Interest income	646,172	47,667	1,405,246	100,778
Total other income, net	642,732	4,825,491	1,401,529	5,522,970
Net (loss) income	$ (4,753,541)	$ 2,150,362	$ (9,584,781)	$ 190,525
Per share information:				
Net (loss) income per share of common stock, basic and diluted	$ (0.55)	$ 0.65	$ (1.22)	$ 0.13
Weighted average shares outstanding, basic and diluted	8,702,764	3,308,302	7,861,757	1,458,415
Net loss per share of common stock, diluted	$ (0.55)	$ (0.70)	$ (1.22)	$ (2.37)
Weighted average shares outstanding, diluted	8,702,764	3,766,700	7,861,757	2,209,407
Comprehensive (loss) income:				
Net unrealized gain on marketable securities	142,864	—	123,162	—
Total comprehensive (loss) income	$ (4,610,677)	$ 2,150,362	$ (9,461,619)	$ 190,525

Source: CervoMed Inc.