CervoMed Reports Second Quarter 2024 Financial Results and Provides Corporate Updates

August 12, 2024

- 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, Aug. 12, 2024 (GLOBE NEWSWIRE) -- 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 patients screened met the exclusion criteria for plasma ptau181—that is, they did not have advanced DLB—affirming our expectation that half or more of individuals with diagnosed DLB are still 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 demonstrating neflamapimod's potential to improve the lives of patients by targeting synaptic dysfunction in the basal forebrain cholinergic system to address cognitive, functional and motor aspects of the disease, and we believe a positive result in RewinD-LB will bring us one step closer to the market in this high value indication. Beyond DLB, we continue to explore additional opportunities to capitalize on neflamapimod's potential to overcome existing challenges in neurological disorders driven by cholinergic dysfunction. This includes progressing early-stage clinical activities evaluating neflamapimod's potential to promote recovery from ischemic stroke and improve clinical outcomes in certain forms of frontotemporal dementia."

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 Position: As of June 30, 2024, CervoMed had approximately $50.9 million in cash, cash equivalents and marketable securities, as compared to approximately $7.8 million as of December 31, 2023. The increase in cash on-hand 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 June 30, 2024, along with the remaining funds to be received from its 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 National Institute 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 active during the current year period. CervoMed initiated the RewinD-LB Trial in the second quarter of 2023 and completed enrollment in June 2024, with trial sites being activated 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 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 second quarter of 2023 and the completion of enrollment in June 2024.

General and Administrative (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 attributable to increased public company costs, including legal costs, insurance costs, headcount costs, stock-based compensation expense due to additional stock options granted and an amendment to a former executive's previously granted option awards to extend the vesting and exercise periods thereunder, and investor/public relations costs following the completion of CervoMed's reverse merger and commencement of trading as a public company in the third quarter of 2023.

Operating Loss: Operating 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, 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 $21.0 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 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, 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 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.

Investor Contact:
PJ Kelleher
LifeSci Advisors
Investors@cervomed.com
617-430-7579

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)

Source: CervoMed Inc.