CervoMed Reports Third Quarter 2023 Financial Results and Business Highlights

November 13, 2023

Dosed first patient in Phase 2b RewinD-LB study evaluating neflamapimod in patients with dementia with Lewy bodies (DLB)

Multiple peer-reviewed journal publications and a conference presentation inform on the potential of neflamapimod in DLB and probability of success in optimized RewinD-LB study

Completed reverse merger; company now publicly traded on Nasdaq ("CRVO")

CervoMed has cash runway through the end of 2024, by which time the topline primary efficacy results from the Phase 2b RewinD-LB study are expected to be available

BOSTON, Nov. 13, 2023 /PRNewswire/ -- CervoMed Inc. (NASDAQ: CRVO), a clinical stage company focused on developing treatments for degenerative diseases of the brain, today announced financial results for the third quarter ended September 30, 2023, and provided recent business highlights.

"This has been an active and exciting quarter as we completed our merger and launch of CervoMed, while also enrolling the first patient in our RewinD-LB Phase 2b study of neflamapimod for dementia with Lewy bodies (DLB)," said John Alam, MD, Chief Executive Officer of CervoMed. "The Company has the operational capability to conduct the RewinD-LB study at the highest level and is funded through to the end of 2024, by which time we expect to have available the topline primary efficacy data read-out in the study, an important and high-value milestone for CervoMed."

Ole Isacson, MD, PhD, Professor of Neurology and Neuroscience at Harvard Medical School and Chair of the Scientific Advisory Board at CervoMed commented, "The multiple publications in prominent scientific and medical journals as well as the oral presentation at the Clinical Trials in Alzheimer's Disease (CTAD) conference, further reinforce the case for advancing neflamapimod as a treatment for DLB. As discussed in the presentation at CTAD, with the analyses and valuable insight from Phase 2a, the Phase 2b RewinD-LB study, particularly through the focus on patients with pure DLB, has been optimized to demonstrate a very robust treatment effect in this devastating disease."

Third Quarter 2023 and Recent Highlights

R&D Highlights

- **Dosed first patient in RewinD-LB Phase 2b clinical trial.** In August 2023, the first patient was dosed in CervoMed's Rewind-LB Phase 2b clinical trial evaluating neflamapimod in DLB. The RewinD-LB study is a randomized, 16-week double-blind, placebo-controlled trial of neflamapimod in 160 patients with prodromal DLB or mild dementia due to DLB. Neflamapimod will be administered orally, 40 mg three-times-daily, with half the participants receiving matching placebo in the main study. All patients who complete the main, placebo-controlled portion of the study will receive an additional 32 weeks of neflamapimod treatment on an open label basis. The study is expected to complete enrollment in the first half of 2024 with initial data from the placebo-controlled portion of the study expected in the second half of 2024. More information, including information on active clinical trial sites, on the RewinD-LB study is available at clinicaltrials.gov.
- **Publication in *Neurology*® of Phase 2a Results Stratified by Plasma Phosphorylated Tau Status at Baseline Strengthens the Case for Progressing Neflamapimod as a Disease-Modifying Treatment for DLB.** In October 2023, *Neurology*®, the medical journal of the American Academy of Neurology, published a paper demonstrating that the magnitude of the neflamapimod treatment effect in the DLB Phase 2a study in the sub-group with normal plasma ptau181 at study entry [i.e., those with pure DLB, without biomarker evidence of Alzheimer's Disease (AD) related co-pathology] was greater than that seen in the overall study population and substantial, with a treatment effect size relative to placebo of at least 0.7 (indicative of a large effect) for each of the measures of dementia severity, attention, recognition memory, and functional mobility. CervoMed utilized this knowledge in designing the ongoing Phase 2b clinical trial to exclude patients with abnormal levels of plasma ptau181 to increase the probability of success in the trial.
- **Oral presentation at CTAD 2023 informs on ability to demonstrate proof-of-concept in Phase 2b Study.** In October 2023, at the 16th Annual CTAD conference, Dr. Niels Prins, Director of the Brain Research Center in Amsterdam, gave an oral presentation in which he comprehensively reviewed the findings from the Phase 2a AscenD-LB study and discussed the analyses used to optimize the Phase 2b study design for the treatment of patients with DLB. New data in the presentation showed in the Phase 2a study, in patients without AD related co-pathology (assessed by plasma ptau181) at study entry, neflamapimod treatment led to significant improvement compared to placebo in the change in plasma levels of glial fibrillary acidic protein (GFAP), a potential marker of disease progression in DLB. Sample size calculations, as discussed in the presentation, show that the RewinD-LB Phase 2b study has greater than a 95% probability of meeting the primary objective of demonstrating improvement relative to placebo on change in CDR-SB over the course of the study.
- **Published article in *Molecular Neurodegeneration*® on the potential of neflamapimod in AD and DLB.** In October 2023, *Molecular Neurodegeneration*® published a research highlight article that reviewed the preclinical and clinical data in the *Neurology*® publication and a prior publication in *Nature Communications* and concluded that the findings are "a major translational step forward" towards treating basal forebrain cholinergic degeneration, the primary pathology in DLB and a contributor to disease expression and/or progression in multiple other central nervous system disorders, including AD.

Corporate Updates

- **Closed reverse merger and began publicly trading as CervoMed.** In August 2023, CervoMed (formerly known as Diffusion Pharmaceuticals Inc.) completed its previously announced merger with EIP Pharma, Inc. and began trading as a combined company on the Nasdaq Capital Market under the ticker symbol "CRVO".

Upcoming Anticipated Milestones

- Completion of patient enrollment into the RewinD-LB Phase 2b clinical study in DLB in the first half of 2024
- Reporting of initial data from placebo-controlled portion of the RewinD-LB study during the second half of 2024

Third Quarter 2023 Financial Results

Cash Position: As of September 30, 2023, CervoMed had $10.4 million in cash and cash equivalents, as compared to $4.1 million as of December 31, 2022. The Company currently expects its cash position as of September 30, 2023, along with the remaining funds to be received from the National Institutes of Health's National Institute on Aging (NIA) grant received by the Company in January 2023, will enable it to fund its operating expenses and capital expenditures through the end of 2024, by which time the topline primary efficacy results of the Phase 2b clinical data from the RewinD-LB trial are expected to be available.

Grant Revenue: Grant revenue was $1.5 million for the three months ended September 30, 2023, compared to no revenue for the same period in 2022.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2023 were $1.8 million, compared to $0.3 million in the third quarter of 2022. This increase was attributed to the RewinD-LB Phase 2b clinical study in DLB, which began in the first quarter of 2023.

General and Administrative (G&A) Expenses: G&A expenses were $2.4 million during the third quarter of 2023 versus $0.6 million in the third quarter of 2022. This increase was attributable to the additional costs related to the reverse merger, compensation for additional headcount, and professional service fees.

Operating Loss: Operating loss was $2.7 million for the three months ended September 30, 2023, compared to $0.9 million for the same period in 2022.

Net Income: Net income was $2.2 million for the three months ended September 30, 2023, compared to a net loss of $0.9 million for the same period in 2022. The net income in the quarter was driven by a noncash gain recognized for the conversion of the convertible notes upon the execution of the merger, which was based on the stock price on the date of the transaction.

About Neflamapimod

Neflamapimod is an investigational drug that is an orally administered small molecule brain penetrant that inhibits p38MAP kinase alpha (p38α). P38α, which is expressed in neurons under conditions of stress and disease, plays a major role in inflammation-induced synaptic toxicity, leading to synaptic dysfunction. Neflamapimod is currently being developed for the treatment of dementia with Lewy bodies (DLB) and is the first treatment with the potential to have a positive impact on cognition, function and motor function.

In preclinical studies, neflamapimod reversed synaptic dysfunction, including and particularly within the part of the brain most impacted in DLB – the basal forebrain cholinergic system. In Phase 1 and Phase 2 clinical studies involving more than 300 participants, neflamapimod has been shown to be generally well tolerated. Results from the AscenD-LB Phase 2a clinical study demonstrated that neflamapimod significantly improved dementia severity compared to placebo and showed significant improvement on motor function compared to placebo. At the highest dose evaluated, neflamapimod improved cognition. The clinical effects of neflamapimod in the Phase 2a study were most prominent in patients with pure DLB (i.e., those without AD co-pathology). The combined preclinical and clinical data are consistent with neflamapimod treating the underlying DLB disease process and suggest it has the potential to be the first disease-modifying treatment for DLB.

Patient enrollment is ongoing in the RewinD-LB Phase 2b clinical trial of neflamapimod, a 160-patient clinical study that is funded by a $21 million grant from the National Institutes of Health's National Institute on Aging (NIA) The NIA grant funds will be disbursed over the course of study as the costs are incurred. Neflamapimod was granted Fast Track status by the U.S. Food and Drug Administration for the treatment of DLB.

About CervoMed

CervoMed Inc. is a clinical-stage biotechnology company focused on developing treatments for degenerative diseases of the brain. The Company is currently developing neflamapimod, an investigational orally administered small molecule brain penetrant that inhibits p38MAP kinase alpha (p38a). Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in dementia with Lewy bodies (DLB) and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with DLB. EIP Pharma, Inc. is a wholly owned subsidiary of CervoMed.

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 CervoMed Inc. (the "Company"), including, but not limited to, the therapeutic potential of neflamapimod; anticipated milestones related to the Company's clinical development programs, including timelines for trial enrollment and reporting of data; the potential therapeutic value of neflamapimod; the Company's anticipated cash runway; and the potential commercial opportunity of neflamapimod, if approved. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential" or other words that convey uncertainty of future events or outcomes 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 Company's ability to design, initiate, enroll, execute, and complete its planned studies evaluating neflamapimod; 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 Company's ability to maintain its listing on the Nasdaq Capital Market, as well as comply with applicable Nasdaq rules and regulations; the market price of the Company's securities, which may be volatile due to a variety of factors, including changes in the competitive and highly regulated industry in which the Company operates; variations in operating performance across competitors; changes in laws and regulations affecting the Company's business; the Company's ability to remediate its previously disclosed material weaknesses in its internal controls over financial reporting in a timely manner; the Company's ability to successfully integrate the historical businesses of EIP and Diffusion and realize the anticipated benefits of the merger; 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, including the continued availability of funding for the U.S. federal government to support disbursements under the Company's NIA grant; and the other factors discussed under the heading "Risk Factors" in the Company's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on November 13, 2023, and other filings that the Company may file from time to time with the SEC. Any forward-looking statements in this release speak to the date hereof (or such earlier date as may be identified) and the Company does not undertake any obligation to update such forward-looking statements to reflect events or circumstances

after the date of this release, except to the extent required by law.

CervoMed Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 10,424,675	$ 4,093,579
Prepaid expenses and other current assets	1,418,745	64,127
Total current assets	11,843,420	4,157,706
Other assets	194,443	-
Total assets	$ 12,037,863	$ 4,157,706
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 533,790	$ 97,302
Deferred grant revenue	547,051	-
Accrued expenses and other current liabilities	1,382,822	644,252
Convertible Notes	-	12,414,000
Total liabilities	2,463,663	13,155,554
Commitments and contingencies (Note 10)		
Convertible preferred stock:		
Series preferred stock $0.001 par value; 30,000,000 shares authorized 0 shares issued and outstanding at September 30, 2023 and December 31, 2022	-	-
Series A-1 preferred stock $0.001 par value; 1,960,600 shares authorized; 0 and 1,960,600 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	246,849
Series A-2 preferred stock, $0.001 par value; 335,711 shares authorized; 0 and 335,711 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	4,173,267
Series B preferred stock, $0.001 par value; 1,034,890 shares authorized; 0 and 1,034,890 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	19,867,095
Total convertible preferred stock	-	24,287,211
Stockholders' equity (deficit):		
Common stock, $0.001 par value: 1,000,000,000 shares authorized, 5,674,354 and 518,140 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	5,674	518
Additional paid-in capital	61,646,917	18,983,339
Accumulated deficit	(52,078,391)	(52,268,916)
Total stockholders' equity (deficit)	$ 9,574,200	-33,285,059
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 12,037,863	$ 4,157,706

CervoMed Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30		Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant revenue	$ 1,526,482	$ -	$ 4,654,294	$ -
Operating expenses:				
Research and development	1,791,487	330,543	5,583,149	955,784
General and administrative	2,410,124	573,511	4,403,590	1,580,927
Total operating expenses	4,201,611	904,054	9,986,739	2,536,711
Loss from operations	(2,675,129)	(904,054)	(5,332,445)	(2,536,711)
Other income (expense):				
Other income (expense)	4,777,824	(88)	5,422,192	(1,769,093)
Interest income	47,667	21,519	100,778	30,157
Total other income (expense)	4,825,491	21,431	5,522,970	(1,738,936)
Net income (loss)	$ 2,150,362	$ (882,623)	$ 190,525	$ (4,275,647)
Per share information:				

Net income (loss) per share of common stock - basic	$ 0.65	$ (1.70)	$ 0.13	$ (8.25)
Weighted average shares outstanding - basic	3,308,302	518,140	1,458,415	518,140
Net income (loss) per share of common stock - diluted	$ (0.70)	$ (1.70)	$ (2.37)	$ (8.25)
Weighted average shares outstanding - diluted	3,766,700	518,140	2,209,407	518,140

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