CervoMed Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Updates

April 01, 2024

- Announced private placement of up to $149.4 million led by RA Capital Management with participation from Armistice Capital, Special Situations Funds and Soleus Capital; pro forma cash and cash equivalents from upfront proceeds expected to provide runway through the end of 2025

- CervoMed on track to complete enrollment in 2Q 2024 in its RewinD-LB Phase 2b clinical trial evaluating neflamapimod in patients with dementia with Lewy bodies (DLB); topline data expected in 4Q 2024

- Integrated summary of results from AscenD-LB Phase 2a trial published in peer-reviewed journal and presentations at a major scientific conference further inform on the potential of neflamapimod in DLB and probability of success in RewinD-LB

- Appointed Joshua Boger, Ph.D., as Chair of the Board of Directors; Dr. Boger is the founder and former CEO of Vertex Pharmaceuticals

BOSTON, April 01, 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 fourth quarter and full year ended December 31, 2023.

"In 2023, we made transformative advancements to build our business, including successfully listing on NASDAQ and have begun 2024 by strengthening our leadership with the appointment of industry veteran, Joshua Boger, Ph.D., as non-executive Chair of the Board," said John Alam, MD, Chief Executive Officer of CervoMed. "With this momentum, we look forward to building on recent publications that position our lead clinical program, neflamapimod, as a highly differentiated, first-to-market treatment option for patients with DLB. Our RewinD-LB Phase 2b trial is well powered, designed to include patients most likely to benefit from neflamapimod, and is expected to provide a path to market in this high value indication. We remain on track to fully enroll the RewinD-LB trial within the second quarter of this year, followed by availability of topline efficacy results in the fourth quarter of 2024."

Recent Highlights and Anticipated Milestones

- Enrollment in the randomized, controlled Phase 2b RewinD-LB trial evaluating oral neflamapimod in patients with DLB continues to progress and the Company remains on track to complete enrollment in the second quarter of 2024.
- At the International Conference on Alzheimer's & Parkinson's Diseases (AD/PD) in March 2024, the Company presented data from the AscenD-LB Phase 2a trial in a poster demonstrating that, neflamapimod treatment led to significant improvement compared to placebo in the change in plasma levels of glial fibrillary acidic protein (GFAP) in patients with pure DLB. Moreover, the neflamapimod treatment effects on GFAP were correlated to clinical outcomes, assessed by the CDR-SB.
    - In a separate presentation at AD/PD, scientific collaborators from University College London presented data demonstrating neflamapimod improves axonal transport in a transgenic mouse model of frontotemporal dementia.
    - CervoMed's CEO, John Alam, MD, participated in a panel discussion at AD/PD titled, "New Insights in the Development of Biomarkers, Imaging, and Therapy of Alpha-synuclein, LRKK2, and GBA Pathologies."
- Integrated summary of results from the AscenD-LB Phase 2a trial evaluating treatment with neflamapimod in patients with DLB were published in *the Journal of Prevention of Alzheimer's Disease (JPAD)* in February 2024. The manuscript is available online and along with the integrated summary, includes the first peer reviewed publication of positive electroencephalogram and MRI data with neflamapimod treatment.
    - The ongoing RewinD-LB study was designed based on key learnings from the Phase 2a AscenD-LB trial of neflamapimod, including the use of a single dose regimen of neflamapimod 40mg three-times-a-day (TID), enrolling patients with pure DLB (with pre-treatment plasma ptau181 below cutoff) and selecting the Clinical Dementia Rating Sum of Boxes (CDR-SB) scale as the primary endpoint. The RewinD-LB trial also includes the use of structural and functional MRI in a 40-patient subgroup to assess treatment effects on atrophy of the basal forebrain, as well its functional connectivity.

Corporate Update

- On March 28, 2024, the Company announced entry into a securities purchase agreement pursuant to which it agreed to sell an aggregate of 2,532,285 units (the "Units"), each Unit comprised of (i) (A) one share of its common stock or (B) one pre-funded warrant to purchase one share of common stock, and, in each case, (ii) one Series A warrant to purchase one share of common stock to a select group of institutional and accredited healthcare specialist investors led by RA Capital Management in a private placement. Each Unit will have a purchase price of $19.745 (or $19.744 in the case of Units that include a pre-funded warrant in lieu of common stock). The Company anticipates the aggregate upfront gross proceeds from the private placement will be approximately $50 million, before deducting any offering-related fees and expenses, and up to approximately $99.4 million in additional aggregate gross proceeds if the Series A warrants are fully exercised for cash. The Series A warrants have an initial exercise price of $39.24 per share, representing a 100% premium to the last sale on March 27, 2024, will be immediately exercisable, and will expire at the earlier of (i) April 1, 2027 or (ii) 180 days after the date that the Company makes a public announcement of positive top-line data from the Company's Phase 2b RewinD-LB clinical trial evaluating neflamapimod for treatment of patients with dementia with Lewy bodies ("DLB"). The private placement is expected to close on or about April 1, 2024, subject to customary closing conditions.
- Appointed industry leader Joshua Boger, Ph.D., as non-executive Chair of the Board. Dr. Boger is an industry veteran who has served in multiple scientific and business leadership roles in his 40+ year career. Notably, he is the founder and former CEO of Vertex Pharmaceuticals.

Full Year 2023 Financial Results

Cash Position: As of December 31, 2023, CervoMed had $7.8 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 December 31, 2023, along with the remaining funds to be received from the NIA grant

received and the upfront private placement funding of $50.0 million announced March 28, 2024, and expected to be received by the Company on April 1, 2024, will enable it to fund its operating expenses and capital expenditures through the end of 2025.

Grant Revenue: Grant revenue was $7.1 million for the year ended December 31, 2023, compared to no revenue for the same period in 2022.

Research and Development (R&D) Expenses: R&D expenses for the year ended December 31, 2023, were $8.4 million, compared to $1.3 million for the year ended December 31, 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 $6.5 million for the year ended December 31, 2023, versus $2.1 million for the year ended December 31, 2022. This increase was attributable to the additional costs related to the reverse merger, which closed in August 2023, compensation for additional headcount, and professional service fees.

Operating Loss: Operating loss was $7.8 million for the year ended December 31, 2023, compared to $3.4 million for the year ended December 31, 2022.

Net Loss: Net Loss was $2.2 million for the year ended December 31, 2023, compared to a net loss of $5.8 million for year ended December 31, 2022. The lower net loss in 2023 versus 2022 was driven by a noncash gain recognized for the conversion of the convertible notes upon the closing of the reverse merger, which was based on the stock price on the date of the transaction.

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 up to 160 patients with very mild or mild dementia due to DLB. 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. Patients with AD-related co-pathology, assessed by a blood biomarker (plasma ptau181), will be excluded. The primary endpoint in the study is change in CDR-SB, 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 million grant from the National Institutes of Health's National Institute on Aging, which will be disbursed over the course of the study as costs are incurred. The study includes 41 sites (30 in the United States, 8 in the United Kingdom, and 3 in the Netherlands), all of which have been initiated. More information on the RewinD-LB study, including contact information on active clinical trial sites, is available at clinicaltrials.gov.

About CervoMed
CervoMed Inc. 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 p38MAP 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 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 therapeutic potential of neflamapimod, the anticipated timing and achievement of clinical and development milestones, including the completion and achievement of primary endpoints of the Company's Phase 2b clinical trial, the anticipated timing, size, closing and receipt of proceeds from the pending private placement transaction, expectations regarding market conditions, the satisfaction of customary closing conditions related to the private placement and the anticipated use of proceeds therefrom, and projected cash runway. 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 results of the Company's clinical trials; 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. This press release shall not constitute an offer to sell or the solicitation of an offer to buy Company securities, nor shall there be any offer, solicitation or sale of Company securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

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CervoMed Inc.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,792,846	$ 4,093,579
Prepaid expenses	1,256,501	64,127
Grant receivable	915,404	-
Total current assets	9,964,751	4,157,706
Other assets	7,770	-

Total assets	$ 9,972,521	$ 4,157,706
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 662,471	$ 97,302
Accrued expenses and other current liabilities	1,933,276	644,252
Convertible notes	-	12,414,000
Total liabilities	2,595,747	13,155,554
Commitments and Contingencies (Note 10)		
Convertible preferred stock:		
Series A preferred stock $0.001 par value; 30,000,000 and 0 shares authorized at December 31, 2023 and 2022, respectively, 0 shares issued and outstanding at December 31, 2023 and December 31, 2022	-	-
Series A-1 preferred stock, $0.001 par value; 0 and 1,960,600 shares authorized at December 31, 2023 and 2022, respectively; 0 and 1,960,600 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	-	246,849
Series A-2 preferred stock, $0.001 par value; 0 and 335,711 shares authorized at December 31, 2023 and 2022, respectively; 0 and 335,711 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	-	4,173,267
Series B preferred stock, $0.001 par value; 0 and 1,034,890 shares authorized at December 31, 2023 and 2022, respectively; 0 and 1,034,890 shares issued and outstanding at December 31, 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 and 4,163,600 shares authorized as of December 31, 2023 and 2022, respectively, 5,674,520 and 518,140 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	5,674	518
Additional paid-in capital	61,811,889	18,983,339
Accumulated deficit	(54,440,789)	(52,268,916)
Total stockholders' equity (deficit)	$ 7,376,774	(33,285,059)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 9,972,521	$ 4,157,706

CervoMed Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2023	**2022**
Grant revenue	$ 7,144,872	$ -
Operating expenses:		
Research and development	8,438,499	1,336,469
General and administrative	6,519,268	2,139,065
Total operating expenses	14,957,767	3,475,534
Loss from operations	(7,812,895)	(3,475,534)
Other income (expense):		
Other income (expense)	5,421,592	(2,389,152)
Interest income	219,430	62,226
Interest expense	-	(587)
Total other income (expense)	5,641,022	(2,327,513)
Net loss	$ (2,171,873)	$ (5,803,047)
Per share information:		
Net loss per share of common stock - basic and diluted	$ (0.82)	$ (11.20)
Weighted average shares outstanding - basic and diluted	2,661,416	518,140

Source: CervoMed Inc.