Minerva Neurosciences Reports Fiscal Year 2022 Fourth Quarter And Year End Financial Results And Business Updates

March 8, 2023

Company to Host Conference Call Today at 8:30 a.m. ET

BURLINGTON, Mass., March 08, 2023 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system disorders, today reported business updates and financial results for the fourth quarter and year ended December 31, 2022.

Corporate Update

"In 2022, we had multiple interactions with the FDA regarding the regulatory path forward for our lead compound, roluperidone. After submitting an NDA for roluperidone to the FDA in August, we received a Refuse to File letter (RTF) in the fall, which was upheld following another meeting with the FDA. We remain committed to developing roluperidone as a potentially transformative treatment for those patients with negative symptoms of schizophrenia and we anticipate further discussion with the FDA over the coming months," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

Roluperidone

- In March 2022, Minerva attended a Type C meeting with the FDA, who advised that certain concerns remained, which were outlined in our press release on April 7, 2022, specifically:
  - The applicability of the Phase 2b data (conducted outside of the U.S). to the U.S. population;
  - The Phase 3 study did not meet its primary endpoint;
  - FDA sought reassurance that Minerva could reliably identify patients who do not need antipsychotics and how to evaluate the stability of those patients; and
  - The FDA also noted that roluperidone might be used by prescribers in a way that differs significantly from the intended monotherapy use and that the sponsor had not presented data to show that roluperidone would not interfere with the safety or efficacy of antipsychotic medications.
- In August 2022, the Company submitted the NDA for roluperidone. Additional data were provided which the Company believed addressed the concerns raised by FDA at the April 2022 Type C meeting. The submission was supported by results from two late-stage, well-controlled studies in patients with moderate to severe negative symptoms and stable positive symptoms of schizophrenia.
- In October 2022, Minerva received a RTF from the FDA. Consequently, a Type A meeting was requested to discuss the RTF, which was held on November 30, 2022. Following the Type A meeting, the FDA confirmed that the RTF remains in effect.

Fourth Quarter and Year End Financial Results

- **Net loss:** Net loss for the fourth quarter ended December 31, 2022 was $6.7 million, or a loss per share of $1.26 (basic and diluted), as compared to a net loss of $21.3 million for the fourth quarter ended December 31 2021, or a loss per share of $3.99 (basic and diluted). For the year ended December 31, 2022, net loss was $32.1 million, or a loss per share of $6.01 (basic and diluted), versus a net loss of $49.9 million for the year ended December 31, 2021, or a loss per share of $9.35 (basic and diluted).
- **Research and development (R&D) expense**: R&D expense for the fourth quarters ended December 31, 2022 and 2021 was $3.2 million and $18.7 million, respectively, a decrease of $15.5 million. The decrease in R&D expense was primarily due to an impairment charge of $15.2 million in the fourth quarter of 2021 to the carrying value of in-process research and development related to the MIN-301 development program.

  R&D expense for the years ended December 31, 2022 and 2021 was $14.6 million and $32.0 million, respectively, a decrease of $17.4 million. The decrease in R&D expense was primarily due to an impairment charge of $15.2 million in the fourth quarter of 2021 to the carrying value of in-process research and development related to MIN-301, as well as lower clinical trial costs during 2022. Non-cash stock compensation costs included within R&D expense for the years ended December 31, 2022 and 2021 was $2.0 million and $2.4 million, respectively.
- **General and administrative (G&A) expense:** G&A expense for the fourth quarters ended December 31, 2022 and 2021 was $1.9 million and $2.6 million, respectively, a decrease of $0.7 million. G&A expense for the years ended December 31,

2022 and 2021 was $10.6 million and $13.3 million, respectively, a decrease of $2.7 million. The decrease in G&A expense for both the fourth quarter and year ended December 31, 2022 versus the prior year periods was primarily due to lower compensation expense and lower legal and insurance fees. Non-cash stock compensation costs included in G&A expense for the years ended December 31, 2022 and 2021 was $2.1 million and $2.8 million, respectively.

- **Cash Position:** Cash, cash equivalents, and restricted cash as of December 31, 2022 were approximately $36.2 million, compared to $60.9 million as of December 31, 2021. In January 2023, we received a refund of our NDA filing fee of $3.1 million from the FDA. This refund was made in accordance with the Federal Food Drug and Cosmetic Act, which allows a fee waiver for a small business submitting its first human drug application.

Conference Call Information:

The live conference call will begin this morning at 8:30 a.m. ET and may be accessed here and on the Company's website under Events and Presentations.

The archived webcast will be available on the Company's website beginning approximately two hours after the event for 90 days.

About Minerva Neurosciences

Minerva Neurosciences, Inc. (Nasdaq: NERV) is a clinical-stage biopharmaceutical company focused on developing product candidates to treat central nervous system (CNS) diseases. Our goal is to transform the lives of patients with improved therapeutic options. Minerva's portfolio of compounds includes roluperidone (MIN-101), for negative symptoms of schizophrenia, and MIN-301, for Parkinson's disease. For more information, please visit our website.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this press release, and involve certain risks and uncertainties. Forward-looking statements include, but are not limited to, statements herein with respect to the clinical and therapeutic potential of roluperidone (MIN-101); and the expectations regarding continued conversation with the FDA with respect to roluperidone and the timing thereof. These forward-looking statements are based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, whether roluperidone will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the FDA or equivalent foreign regulatory agencies and for which indications; whether we will be able to continue the discussion with the FDA regarding our NDA submission for roluperidone and the outcome thereof; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations and corporate objectives on terms acceptable to us; general economic conditions; and other factors that are described under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 8, 2023. Copies of reports filed with the SEC are posted on our website at www.minervaneurosciences.com. The forward-looking statements in this press release are based on information available to us as of the date hereof, and we disclaim any obligation to update any forward-looking statements, except as required by law.

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 36,094	$ 60,755
Restricted cash	100	100
Refundable regulatory fee	3,117	-
Prepaid expenses and other current assets	848	1,346
Total current assets	40,159	62,201
Equipment & capitalized software, net	59	52
Goodwill	14,869	14,869
Total Assets	$ 55,087	$ 77,122

LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY

Current Liabilities:		
Accounts payable	$ 969	$ 1,853
Accrued expenses and other current liabilities	408	966
Total current liabilities	1,377	2,819
Long-Term Liabilities:		
Liability related to the sale of future royalties	73,734	66,327
Total liabilities	75,111	69,146
Stockholders' (Deficit) Equity:		
Common stock	1	1
Additional paid-in capital	346,785	342,676
Accumulated deficit	(366,810)	(334,701)
Total stockholders' (deficit) equity	(20,024)	7,976
Total Liabilities and Stockholders' (Deficit) Equity	$ 55,087	$ 77,122

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31, (in thousands, except per share amounts)		Twelve Months Ended December 31 (in thousands, except per share amounts)	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 3,190	$ 18,746	$ 14,649	$ 32,039
General and administrative	1,880	2,631	10,582	13,327
Total operating expenses	5,070	21,377	25,231	45,366
Loss from operations	(5,070)	(21,377)	(25,231)	(45,366)
Foreign exchange loss	(28)	(4)	(28)	(33)
Investment income	297	4	557	17
Non-cash interest expense for the sale of future royalties	(1,925)	(1,733)	(7,407)	(6,327)
Loss before income taxes	(6,726)	(23,110)	(32,109)	(51,709)
Benefit for income taxes	-	1,803	-	1,803
Net loss	(6,726)	(21,307)	(32,109)	(49,906)
Net loss per share, basic and diluted	$ (1.26)	$ (3.99)	$ (6.01)	$ (9.35)
Weighted average shares outstanding, basic and diluted	5,340	5,340	5,340	5,340