Minerva Neurosciences Reports 2023 First Quarter Financial Results and Business Updates

May 15, 2023

Company to host conference call today at 8:30 a.m. ET

BURLINGTON, Mass., May 15, 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 first quarter ended March 31, 2023.

“The first quarter saw the achievement of a significant milestone for our investigational drug, roluperidone, and for Minerva, as the U.S. Food and Drug Administration (FDA) filed our New Drug Application (NDA) for roluperidone for the treatment of negative symptoms of schizophrenia on April 27, 2023. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2024. We believe roluperidone has a unique mechanism of action and is intended to treat a group of patients that, to date, have not had an approved treatment. This is a completely new approach to treating negative symptoms of schizophrenia and we look forward to continuing to work with the FDA as they undertake their review.

“Successfully treating the negative symptoms of schizophrenia has historically been a significant challenge. If approved, roluperidone will be the first approved treatment for negative symptoms of schizophrenia in the U.S. We believe it has the potential to beneficially impact patients’ quality of life, reduce the burden on families and caregivers and provide physicians with a new treatment option,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

Recent Business Highlights

- The Company submitted a Formal Dispute Resolution Request (FDRR) on March 2, 2023, and met with the FDA on March 28, 2023. At the meeting the Company presented a detailed summary of data to address the issues raised in the Refuse to File letter (RTF) received by the Company in October 2022.
- On April 27, 2023, the FDA confirmed filing of Minerva’s NDA for roluperidone for the treatment of negative symptoms in patients with schizophrenia.
- On May 8, 2023, the FDA confirmed that they had assigned a PDUFA goal date of February 26, 2024.

First Quarter 2023 Financial Results

- **Research and development (R&D) expense**: Research and development expenses were $2.7 million and $5.0 million for the three months ended March 31, 2023 and 2022, respectively, a decrease of approximately $2.3 million. The decrease in research and development expenses was primarily due to lower non-cash stock compensation costs, and lower consultant and contractor fees related to the NDA that was submitted during 2022. Non-cash stock compensation expense included in research and development expenses was $0.2 million and $0.5 million for the three months ended March 31, 2023 and 2022, respectively.

- **General and administrative (G&A) expense:** General and administrative expenses were $2.7 million and $3.0 million for the three months ended March 31, 2023 and 2022, respectively, a decrease of approximately $0.3 million. The decrease in general and administrative expenses was primarily due to lower non-cash stock compensation costs and lower insurance costs. Non-cash stock compensation expense included in general and administrative expenses was $0.2 million and $0.6 million for the three months ended March 31, 2023 and 2022, respectively.

- **Non-cash interest expense**: For the three months ended March 31, 2023 and 2022 we recognized non-cash interest expense of $2.0 million and $1.8 million, respectively, an increase of $0.2 million. The increase was primarily due to an increase in the carrying value of the liability related to the sale of future royalties for seltorexant to Royalty Pharma, for which upfront milestone payments are being amortized under the interest method over the estimated life of the agreement.

- **Net loss:** Net loss for the first quarter ended March 31, 2023 was $7.0 million, or a loss per share of $1.31 (basic and diluted), as compared to a net loss of $9.8 million for the first quarter ended March 31, 2022, or a loss per share of $1.83 (basic and diluted).

- **Cash Position:** Cash, cash equivalents, and restricted cash as of March 31, 2023 were approximately $36.1 million, compared to $36.2 million as of December 31, 2022. 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 regulatory progress and therapeutic potential of roluperidone for the treatment of negative symptoms in patients with schizophrenia. 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 the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain regulatory approval; whether the FDA may meet expected review timelines for our NDA; whether roluperidone will be successfully marketed if approved; 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, as updated by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023. Copies of reports filed with the SEC are posted on our website at http://ir.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
(Unaudited, in thousands)

	March 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 35,978	$ 36,094
Restricted cash	100	100
Refundable regulatory fee	-	3,117
Prepaid expenses and other current assets	596	848
Total current assets	36,674	40,159
Equipment & capitalized software, net	52	59
Goodwill	14,869	14,869
Total Assets	$ 51,595	$ 55,087
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 961	$ 969
Accrued expenses and other current liabilities	1,541	408
Total current liabilities	2,502	1,377
Long-Term Liabilities:		
Liability related to the sale of future royalties	75,711	73,734
Total liabilities	78,213	75,111
Stockholders' (Deficit) Equity:		
Common stock	1	1
Additional paid-in capital	347,161	346,785
Accumulated deficit	(373,780)	(366,810)
Total stockholders' (deficit) equity	(26,618)	(20,024)

Total Liabilities and Stockholders' (Deficit) Equity	$ 51,595	$ 55,087

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31, (in thousands, except per share amounts)	
	2023	**2022**
Operating expenses:		
Research and development	$ 2,653	$ 4,960
General and administrative	2,695	3,029
Total operating expenses	5,348	7,989
Loss from operations	(5,348)	(7,989)
Foreign exchange loss	(9)	(4)
Investment income	364	8
Non-cash interest expense for the sale of future royalties	(1,977)	(1,779)
Net loss	(6,970)	(9,764)
Net loss per share, basic and diluted	$ (1.31)	$ (1.83)
Weighted average shares outstanding, basic and diluted	5,340	5,340