Minerva Neurosciences Reports First Quarter 2022 Financial Results and Business Updates

May 4, 2022

Company Expects to Submit an NDA for Roluperidone, Subject to FDA Guidance, in the Third Quarter of 2022

WALTHAM, Mass., May 04, 2022 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, today reported key business updates and financial results for the quarter ended March 31, 2022.

Roluperidone Update

On April 7, 2022, the Company issued a press release providing an update from the March 2, 2022 Type C Meeting with the Food and Drug Administration (FDA) and next steps in preparation for submission of a New Drug Application (NDA) for roluperidone for the treatment of negative symptoms in schizophrenia. Following the update, the Company hosted a webcast on April 13, 2022, which is archived and can be accessed under "Events and Presentations" in the Investors and Media section of the Company's website.

Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva Neurosciences said, "We had a constructive Type C meeting with the FDA who confirmed that there is a significant unmet need for treatments for negative symptoms of schizophrenia. Patients and medical communities have long recognized the need for a new treatment paradigm to address the debilitating effects of negative symptoms. We are encouraged by the recent meeting with the FDA and we continue to believe that roluperidone has the potential to transform the lives of people who are unable to enjoy everyday activities due to their negative symptoms."

Minerva has conducted two adequate and well controlled studies for the intended indication and are of the opinion that the data from these studies are sufficient to support a marketing application. Following the meeting, the Company submitted additional data to the FDA to address matters discussed at the meeting. The Company is preparing an NDA for roluperidone which, subject to FDA guidance, is currently expected to be submitted in the third quarter of 2022.

First Quarter 2022 Financial Results

- **Net Loss:** Net loss was $9.8 million for the first quarter of 2022, or net loss per share of $0.23 basic and diluted, as compared to net loss of $8.8 million, or net loss per share of $0.21 basic and diluted, for the first quarter of 2021.

- **R&D Expense:** For the three months ended March 31, 2022 and 2021, research and development (R&D) expense was $5.0 million and $3.3 million, respectively, an increase of approximately $1.7 million. For the three months ended March 31, 2022 and 2021, non-cash stock compensation expense included in R&D was $0.5 million and $0.6 million, respectively. The increase in R&D expense was primarily due to higher consulting fees related to NDA support activities.

- **G&A Expense:** For the three months ended March 31, 2022 and 2021, general and administrative (G&A) expense was $3.0 million and $4.2 million, respectively, a decrease of approximately $1.2 million. For the three months ended March 31, 2022 and 2021, non-cash stock compensation expense included in G&A was $0.6 million and $0.9 million, respectively. The decrease in G&A expense was primarily due to lower staffing related expenses, non-cash stock compensation expense, lower legal and insurance costs.

- **Non-cash Interest Expense for the Sale of Future Royalties:** For the three months ended March 31, 2022 and 2021, non-cash interest expense for the sale of future royalties was $1.8 million and $1.3 million, respectively, an increase of approximately $0.5 million. The increase in non-cash interest expense was primarily due to interest accruing with effect from January 19, 2021, the date at which the Company entered into an agreement to sell our royalty interest in seltorexant to Royalty Pharma, an increase in the effective rate from 10.5% to 10.7%, as well as an increase in the underlying balance of the liability. The effective interest rate is based upon estimates which contain significant assumptions regarding the timing and amount of expected royalty and milestone payments that impact the interest expense that will be recognized over the royalty period.

- **Cash Position:** Cash, cash equivalents, and restricted cash as of March 31, 2022 and December 31, 2021 were approximately $55.0 million and $60.9 million, respectively.

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), in clinical development 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 not limited to, statements herein with respect to the clinical development of roluperidone as monotherapy for the treatment of negative symptoms of schizophrenia; the potential benefits of roluperidone; the adequacy and efficacy of our clinical trials and studies with roluperidone, and the sufficiency of the data from such trials and studies to support marketing application; our interpretation of the feedback from the U.S. Food and Drug Administration (FDA); the anticipated timing of New Drug Application (NDA) submission; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the FDA; and management's ability to successfully achieve its goals. 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 we will be able to successfully address the FDA's concerns discussed herein and whether our future interactions with the FDA will have satisfactory outcomes; whether the FDA will support and accept an NDA submission for roluperidone; whether and when, if at all, our NDA for roluperidone, if successfully submitted, will be approved by the FDA; 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 on terms acceptable to us; and general economic conditions. Other factors that may cause our actual results to differ from those expressed or implied in the forward-looking statements in this press release are identified under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the Securities and Exchange Commission on May 4, 2022. 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 expressly disclaim any obligation to update any forward-looking statements, except as required by law.

For more information:

Investor inquiries:
Fred Ahlholm
CFO, Minerva Neurosciences
info@minervaneurosciences.com

Media Inquiries:
Helen Shik
Principal, Shik Communications LLC
helen@shikcommunications.com

CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	March 31, 2022	December 31, 2021
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 54,947	$ 60,755
Restricted cash	100	100
Prepaid expenses and other current assets	650	1,346
Total current assets	55,697	62,201
Capitalized software, net	52	52
Goodwill	14,869	14,869
Total Assets	$ 70,618	$ 77,122
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,586	$ 1,853
Accrued expenses and other current liabilities	1,662	966
Total current liabilities	3,248	2,819
Long-Term Liabilities:		
Liability related to the sale of future royalties	68,106	66,327
Total liabilities	71,354	69,146
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	343,725	342,673
Accumulated deficit	(344,465)	(334,701)
Total stockholders' equity	(736)	7,976
Total Liabilities and Stockholders' Equity	$ 70,618	$ 77,122

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2022	2021
Operating expenses:		
Research and development	$ 4,960	$ 3,259
General and administrative	3,029	4,249
Total operating expenses	7,989	7,508
Loss from operations	(7,989)	(7,508)
Foreign exchange losses	(4)	(5)
Investment income	8	4
Non-cash interest expense for the sale of future royalties	(1,779)	(1,296)
Net loss	$ (9,764)	$ (8,805)
Net loss per share, basic and diluted	$ (0.23)	$ (0.21)
Weighted average shares outstanding, basic and diluted	42,722	42,722