Minerva Neurosciences Reports Second Quarter 2022 Financial Results and Business Updates

August 9, 2022

Company Continues to Prepare for Potential Submission of an NDA for Roluperidone in the Third Quarter of 2022

WALTHAM, Mass., Aug. 09, 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 June 30, 2022.

Roluperidone Update

Following the March 2, 2022 Type C Meeting with the Food and Drug Administration (FDA), the Company issued a press release on April 7, 2022, providing an update and an outline of next steps in preparation for the anticipated submission of a New Drug Application (NDA) for roluperidone for the treatment of negative symptoms in schizophrenia. Following the press release, 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, “Following the Type C meeting last quarter, we continue to be encouraged by our interactions with the FDA and we are preparing our NDA, which is on track for potential submission during the third quarter of 2022. With no treatments currently approved in the US for negative symptoms of schizophrenia, we are committed to addressing this critical need and believe that roluperidone has the potential to improve the lives of people impacted by negative symptoms.”

Minerva has conducted two adequate and well controlled studies for the intended indication and is of the opinion that the data from these studies are sufficient to support a marketing application. Following the Type C meeting, the Company submitted additional data to the FDA to address certain matters discussed at the meeting.

Second Quarter 2022 Financial Results

At the annual meeting of shareholders held on June 10, 2022 shareholders approved a 1 for 8 reverse stock split of the Company’s common stock. The per share numbers below reflect the reverse stock split for both current and comparable prior periods.

- **Net Loss:** Net loss was $8.7 million for the three months ended June 30, 2022, or net loss per share of $1.63 (basic and diluted), as compared to net loss for the three months ended June 30, 2021 of $10.6 million, or net loss per share of $1.98 (basic and diluted).
  Net loss was $18.5 million for the six months ended June 30, 2022, or net loss per share of $3.46 (basic and diluted), as compared to net loss for the six months ended June 30, 2021 of $19.4 million, or net loss per share of $3.63 (basic and diluted).
- **R&D Expense:** For the three months ended June 30, 2022 and 2021, research and development (R&D) expense was $4.1 million and $5.5 million, respectively, a decrease of approximately $1.4 million. For the three months ended June 30, 2022 and 2021, non-cash stock compensation expense included in R&D was $0.5 million and $0.6 million, respectively. The decrease in R&D expense for the three months ended June 30, 2022 versus the prior year period was primarily due to lower costs for the Phase 3 clinical trial of roluperidone as a result of the completion of the 40-Week Open-Label Extension in May 2021.
  For the six months ended June 30, 2022 and 2021, research and development (R&D) expense was $9.1 million and $8.8 million, respectively, an increase of approximately $0.3 million. For the six months ended June 30, 2022 and 2021, non-cash stock compensation expense included in R&D was $1.0 million and $1.3 million, respectively. The increase in R&D expense for the six months ended June 30, 2022 versus the prior year period was primarily due to lower costs for the Phase 3 clinical trial of roluperidone as a result of the completion of the 40-Week Open-Label Extension in May 2021, offset by higher consulting fees related to NDA support activities.
- **G&A Expense:** For the three months ended June 30, 2022 and 2021, general and administrative (G&A) expense was $2.8 million and $3.4 million, respectively, a decrease of approximately $0.6 million. For the three months ended June 30, 2022 and 2021, non-cash stock compensation expense included in G&A was $0.6 million and $0.7 million, respectively.
  For the six months ended June 30, 2022 and 2021, general and administrative (G&A) expense was $5.9 million and $7.7 million, respectively, a decrease of approximately $1.8 million. For the six months ended June 30, 2022 and 2021, non-cash stock compensation expense included in G&A was $1.1 million and $1.6 million, respectively.
  The decrease in G&A expense for both the three and six months ended June 30, 2022 versus the prior year periods was primarily due to lower staffing related expenses, non-cash stock compensation expense, and lower legal and insurance costs.
- **Non-cash Interest Expense for the Sale of Future Royalties:** For the three months ended June 30, 2022 and 2021, non-cash interest expense for the sale of future royalties was $1.8 million and $1.6 million, respectively, an increase of approximately $0.2 million. For the six months ended June 30, 2022 and 2021, non-cash interest expense for the sale of

future royalties was $3.6 million and $2.9 million, respectively, an increase of approximately $0.7 million. The increase in non-cash interest expense for both the three and six months ended June 30, 2022 versus the prior year periods 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, as well as an increase in the underlying balance of the liability, which totaled $69.9 million at June 30, 2022. The effective interest rate is based upon estimates which contain significant assumptions regarding the timing and amount of expected royalty and milestone payments to be recognized over the royalty period.

- **Cash Position:** Cash, cash equivalents and restricted cash as of June 30, 2022 and December 31, 2021 were approximately $49.9 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 June 30, 2022, filed with the Securities and Exchange Commission on August 9, 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.

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	June 30, 2022	December 31, 2021
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 49,754	$ 60,755
Restricted cash	100	100
Prepaid expenses and other current assets	184	1,346
Total current assets	50,038	62,201
Capitalized software, net	52	52
Goodwill	14,869	14,869
Total Assets	$ 64,959	$ 77,122
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		

Accounts payable	$ 1,520	$ 1,853
Accrued expenses and other current liabilities	1,889	966
Total current liabilities	3,409	2,819
Long-Term Liabilities:		
Liability related to the sale of future royalties	69,932	66,327
Total liabilities	73,341	69,146
Stockholders' Equity:		
Common stock	1	1
Additional paid-in capital	344,801	342,676
Accumulated deficit	(353,184)	(334,701)
Total stockholders' equity	(8,382)	7,976
Total Liabilities and Stockholders' Equity	$ 64,959	$ 77,122

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, (in thousands, except per share amounts)		Six Months Ended June 30, (in thousands, except per share amounts)	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 4,132	$ 5,521	$ 9,092	$ 8,780
General and administrative	2,833	3,442	5,862	7,691
Total operating expenses	6,965	8,963	14,954	16,471
Loss from operations	(6,965)	(8,963)	(14,954)	(16,471)
Foreign exchange losses	2	(19)	(2)	(24)
Investment income	72	5	80	9
Non-cash interest expense for the sale of future royalties	(1,827)	(1,612)	(3,606)	(2,908)
Net loss	(8,718)	(10,589)	(18,482)	(19,394)
Net loss per share, basic	$ (1.63)	$ (1.98)	$ (3.46)	$ (3.63)
Weighted average shares outstanding, basic and diluted	5,340	5,340	5,340	5,340