Minerva Neurosciences Reports Third Quarter 2022 Financial Results and Business Updates

November 9, 2022

Company To Host Live Webcast Today at 8:30 a.m. ET

BURLINGTON, Mass., Nov. 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 September 30, 2022.

Roluperidone Update
As announced on August 17, 2022, the company submitted to the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for roluperidone to treat negative symptoms in schizophrenia. The submission included data from two clinical trials, the company's phase 2b and phase 3 studies, in patients diagnosed with schizophrenia with negative symptoms.

On October 17, 2022, the company announced that it had received a refusal to file letter from the FDA. The company has requested a Type A meeting and anticipates that the Type A meeting will occur by the end of this year.

"We believe that a large subset of patients diagnosed with schizophrenia do not require continuous treatment with antipsychotics for positive symptoms yet still suffer negative symptoms. We developed roluperidone as a monotherapy for this patient sub-population. We discussed with the FDA the need for a treatment for this specific sub-population of U.S. patients and the FDA has acknowledged that negative symptoms represent a significant unmet medical need for which there are currently no approved treatments," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva Neurosciences. "While we are disappointed that the FDA did not accept our NDA for roluperidone, the Company looks forward to discussions with the FDA at the Type A meeting."

Third Quarter 2022 Financial Results

- **Net Loss:** Net loss was $6.9 million for the third quarter of 2022, or net loss per share of $1.29 basic and diluted, as compared to net loss of $9.2 million, or net loss per share of $1.72 basic and diluted, for the third quarter of 2021. Net loss was $25.4 million for the nine months ended September 30, 2022, or net loss per share of $4.75 basic and diluted, as compared to net loss of $28.6 million, or net loss per share of $5.36 basic and diluted for the nine months ended September 30, 2021.

- **R&D Expense:** For the three months ended September 30, 2022 and 2021, research and development (R&D) expense was $2.4 million and $4.5 million, respectively, a decrease of approximately $2.1 million. For the three months ended September 30, 2022 and 2021, non-cash stock compensation expense included in R&D was $0.5 million in both periods.

  For the nine months ended September 30, 2022 and 2021, R&D expense was $11.5 million and $13.3 million, respectively, a decrease of approximately $1.8 million. For the nine months ended September 30, 2022 and 2021, non-cash stock compensation expense included in R&D was $1.5 million and $1.8 million, respectively.

  The decrease in R&D expense for both the three and nine-month periods ended September 30, 2022 versus the comparable prior year periods was primarily due to lower costs for the Phase 3 clinical trial of roluperidone due to the completion of the 40-week open-label extension in 2021, partially offset by higher consulting fees in support of the NDA submission in August 2022.

- **G&A Expense:** For the three months ended September 30, 2022 and 2021, general and administrative (G&A) expense was $2.8 million and $3.0 million, respectively, a decrease of approximately $0.2 million. For the three months ended September 30, 2022 and 2021, non-cash stock compensation expense included in G&A was $0.5 million and $0.6 million, respectively.

  For the nine months ended September 30, 2022 and 2021, G&A expense was $8.7 million and $10.7 million, respectively, a decrease of approximately $2.0 million. For the nine months ended September 30, 2022 and September 30, 2021, non-cash stock compensation expense included in G&A was $1.6 million and $2.2 million, respectively.

  The decrease in G&A expense for both the three and nine-month periods ended September 30, 2022 versus the comparable prior year periods was primarily due to lower legal and insurance costs.

- **Non-cash Interest Expense for the Sale of Future Royalties:** For the three months ended September 30, 2022 and 2021, non-cash interest expense for the sale of future royalties was $1.9 million and $1.7 million, respectively, an increase

of approximately $0.2 million. For the nine months ended September 30, 2022 and 2021, non-cash interest expense for the sale of future royalties was $5.5 million and $4.6 million, respectively, an increase of approximately $0.9 million. The increase in non-cash interest expense for both the three and nine months ended September 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 $71.8 million at September 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 September 30, 2022 were approximately $40.3 million, compared to $60.9 million as of December 31, 2021. In September 2022, the Company entered into an Open Market Sale Agreement with Jefferies LLC pursuant to which the Company may offer and sell shares of its common stock, by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During the nine months ended September 30, 2022, no shares of the Company’s common stock were issued or sold under the agreement. As of September 30, 2022, an aggregate of $22.6 million was eligible for sale under the Company’s effective registration statement on Form S-3 (File No. 333-267424). The Company expects that its existing cash and cash equivalents will be sufficient to meet its anticipated capital requirements for at least the next 12 months based on its current operating plan. The assumptions upon which this estimate is based are routinely evaluated and may be subject to change.

Conference Call Information:

The live webcast 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), 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. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements with respect to the clinical development of roluperidone as monotherapy for the treatment of negative symptoms of schizophrenia; the timing and outcomes of future interactions with the FDA; patient prevalence; and our cash runway. 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 a Type A meeting will be granted and whether our future interactions with the FDA will have satisfactory outcomes; 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 September 30, 2022, filed with the Securities and Exchange Commission on November 9, 2022. Copies of reports filed with the SEC are posted on our website: 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)

	September 30, 2022	December 31, 2021
	(in thousands)	

ASSETS

Current Assets:		
Cash and cash equivalents	$ 40,220	$ 60,755
Restricted cash	100	100
Refundable regulatory fee	3,117	-
Prepaid expenses and other current assets	1,404	1,346
Total current assets	44,841	62,201
Capitalized software, net	49	52
Goodwill	14,869	14,869
Total Assets	$ 59,759	$ 77,122

LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY

Current Liabilities:		
Accounts payable	$ 533	$ 1,853
Accrued expenses and other current liabilities	1,664	966
Total current liabilities	2,197	2,819
Long-Term Liabilities:		
Liability related to the sale of future royalties	71,808	66,327
Total liabilities	74,005	69,146
Stockholders' (Deficit) Equity:		
Common stock	1	1
Additional paid-in capital	345,837	342,676
Accumulated deficit	(360,084)	(334,701)
Total stockholders' (deficit) equity	(14,246)	7,976
Total Liabilities and Stockholders' (Deficit) Equity	$ 59,759	$ 77,122

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, (in thousands, except per share amounts)		Nine Months Ended September 30 (in thousands, except per share amounts)	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 2,367	$ 4,513	$ 11,459	$ 13,292
General and administrative	2,840	3,005	8,703	10,696
Total operating expenses	5,207	7,518	20,162	23,988
Loss from operations	(5,207)	(7,518)	(20,162)	(23,988)
Foreign exchange gains (losses)	2	(5)	-	(29)
Investment income	180	4	260	13
Non-cash interest expense for the sale of future royalties	(1,875)	(1,686)	(5,481)	(4,595)
Net loss	$ (6,900)	$ (9,205)	$ (25,383)	$ (28,599)
Net loss per share, basic and diluted	$ (1.29)	$ (1.72)	$ (4.75)	$ (5.36)
Weighted average shares outstanding, basic and diluted	5,340	5,340	5,340	5,340