Minerva Neurosciences Reports Third Quarter 2021 Financial Results and Business Updates

November 8, 2021

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

WALTHAM, Mass., Nov. 08, 2021 (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, 2021.

Roluperidone Update

On November 3, 2021, the Company announced that the U. S. Food and Drug Administration (FDA) denied the company's request for a pre-NDA meeting for roluperidone and responded that a Type C guidance meeting would be more appropriate to discuss the evidence for use of roluperidone as monotherapy for the treatment of negative symptoms in schizophrenia. The Company plans to request a Type C meeting and, subject to the timing of and feedback from the FDA, continues to work towards the submission of a New Drug Application (NDA) in the first half of 2022.

On September 30, 2021, the Company completed and announced results from a pivotal bioequivalence study comparing the roluperidone formulations used in its late-stage Phase 2b and Phase 3 trials and the planned commercial formulation. The planned commercial formulation was tested under both fasted and fed conditions. The study met key pharmacokinetic (PK) objectives, and the data demonstrate bioequivalence across the various formulations.

Management Team Update

In October, the Company promoted Geoff Race, former Executive Vice President, Chief Financial Officer and Chief Business Officer of Minerva, to President. Minerva's Senior Vice President and Chief Accounting Officer, Frederick Ahlholm, was promoted to Chief Financial Officer.

In September, Dr. Ramana Kuchibhatla was appointed Senior Vice President and Head of Research & Development following Dr. Jay Saoud's retirement and transition to an advisory role. This is a key addition to the Company's leadership team which will help support forthcoming interactions with the FDA.

Third Quarter 2021 Financial Results

- **Net Income/Loss:** Net loss was $9.2 million for the third quarter of 2021, or net loss per share of $0.22 basic and diluted, as compared to net loss of $8.1 million, or net loss per share of $0.19 basic and diluted, for the third quarter of 2020. Net loss was $28.6 million for the nine months ended September 30, 2021, or net loss per share of $0.67 basic and diluted, as compared to net income of $9.3 million, or net income per share of $0.23 basic and diluted for the nine months ended September 30, 2020.

  The decreases in net income for both the three and nine month periods ended September 2021, were primarily due to the Company's opting out of its joint development agreement with Janssen Pharmaceutica for seltorexant during the second quarter of 2020. As a result of opting out of the agreement, the Company immediately recognized $41.2 million in collaborative revenue which had previously been included on the balance sheet under deferred revenue.

- **R&D Expense:** For the three months ended September 30, 2021 and 2020, research and development (R&D) expense was $4.5 million and $4.6 million, respectively, a decrease of approximately $0.1 million. For the three months ended September 30, 2021 and 2020, non-cash stock compensation expense included in R&D was $0.5 million and $0.8 million, respectively.

  For the nine months ended September 30, 2021 and 2020, R&D expense was $13.3 million and $18.5 million, respectively, a decrease of approximately $5.2 million. For the nine months ended September 30, 2021 and 2020, non-cash stock compensation expense included in R&D was $1.8 million and $2.2 million, respectively.

  The decrease in R&D expense for both the three and nine month periods ended September 30, 2021 versus the same periods in 2020 was primarily due to lower costs for the Phase 3 clinical trial of roluperidone, for which the three-month core study portion of the trial was completed in May 2020.

- **G&A Expense:** For the three months ended September 30, 2021 and 2020, general and administrative (G&A) expense was $3.0 million and $3.5 million, respectively, a decrease of approximately $0.5 million. For the three months ended September 30, 2021 and 2020, non-cash stock compensation expense included in G&A was $0.6 million and $1.2 million, respectively.

For the nine months ended September 30, 2021 and 2020, G&A expense was $10.7 million and $13.5 million, respectively, a decrease of approximately $2.8 million. For the nine months ended September 30, 2021 and September 30, 2020, non-cash stock compensation expense included in G&A was $2.2 million and $5.6 million, respectively.

The decrease in G&A expense for both the three and nine month periods ended September 30, 2021 was due primarily to non-cash stock compensation charges resulting from certain stock option awards approved in June 2020 as well as from additional stock compensation expense incurred under a severance agreement during 2020.

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of September 30, 2021 were approximately $65.7 million.

Conference Call Information:

Minerva Neurosciences will host a conference call and live audio webcast today at 8:30 a.m. Eastern Time to discuss the quarter and recent business activities. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 3775536.

The live webcast can be accessed under “Events and Presentations” in the Investors and Media section of Minerva’s website. The archived webcast will be available on the 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, in pre-clinical development for Parkinson’s disease. For more information, please visit our website.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements. 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 timing and scope of clinical trials and regulatory review and results and outcomes of such clinical trials and regulatory review with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the U.S. Food and Drug Administration; the sufficiency of our current cash position to fund our operations; 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 roluperidone will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether any of our therapeutic products or seltorexant will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; 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. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed 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, 2021, filed with the Securities and Exchange Commission on November 8, 2021. Copies of reports filed with the SEC are posted on our website in the Investors and Media section. 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.

For more information:

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CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	September 30, 2021	December 31, 2020
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 65,588	$ 25,357
Restricted cash	100	100
Prepaid expenses and other current assets	1,751	1,983
Total current assets	67,439	27,440
Capitalized software, net	51	-
Other noncurrent assets	-	15
Operating lease right-of-use assets	-	102
In-process research and development	15,200	15,200

Goodwill	14,869	14,869
Total Assets	$ 97,559	$ 57,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,201	$ 996
Accrued expenses and other current liabilities	1,882	2,053
Operating leases	-	111
Total current liabilities	3,083	3,160
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Liability related to the sale of future royalties	64,595	-
Total liabilities	69,481	4,963
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	341,468	337,454
Accumulated deficit	(313,394)	(284,795)
Total stockholders' equity	28,078	52,663
Total Liabilities and Stockholders' Equity	$ 97,559	$ 57,626

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)	
	2021	**2020**	**2021**	**2020**
Collaborative revenue	$ -	$ -	$ -	$ 41,176
Operating expenses:				
Research and development	4,513	4,639	13,292	18,488
General and administrative	3,005	3,452	10,696	13,541
Total operating expenses	7,518	8,091	23,988	32,029
(Loss) gain from operations	(7,518)	(8,091)	(23,988)	9,147
Foreign exchange losses	(5)	(27)	(29)	(41)
Investment income	4	5	13	159
Non-cash interest expense for the sale of future royalties	(1,686)	-	(4,595)	-
Net (loss) income	(9,205)	(8,113)	(28,599)	9,265
Net (loss) income per share, basic	$ (0.22)	$ (0.19)	$ (0.67)	$ 0.23
Weighted average shares outstanding, basic	42,722	41,918	42,722	40,199
Net (loss) income per share, diluted	$ (0.22)	$ (0.19)	$ (0.67)	$ 0.23
Weighted average shares outstanding, diluted	42,722	41,918	42,722	40,478

MINERVA NEUROSCIENCES, INC.

Source: Minerva Neurosciences, Inc