Minerva Neurosciences Reports First Quarter 2021 Financial Results and Business Updates

May 12, 2021

Top-line results from the open-label extension of phase 3 monotherapy trial of roluperidone for the treatment of negative symptoms of schizophrenia show continuous improvement in negative symptoms, improved functional ability, favorable safety profile and limited number of psychotic relapses over one year

Pivotal bioequivalence study initiated

WALTHAM, Mass., May 12, 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 March 31, 2020.

Clinical update

On May 11, 2021, the Company announced results of the open-label extension of the phase 3 trial of roluperidone for the treatment of negative symptoms of schizophrenia following the completion of the 40-week open-label extension period. Details are provided in that press release, and key results include:

- Continuous improvement in negative symptoms as measured by Positive and Negative Syndrome Scale (PANSS) Marder Negative Symptom Factor Score (NSFS) observed over one year (12-week double-blind and 40-week open-label periods) in patients receiving both 64 mg and 32 mg doses;
- Continuous improvement in Personal and Social Performance (PSP) total score over one year, suggesting improvement in patients' everyday life functioning;
- Favorable safety profile with few serious adverse events and no evidence of somnolence, extrapyramidal side effects or weight gain;
- Limited number of relapses observed over one year.

The Company has initiated subject screening in a pivotal bioequivalence study that will include approximately 48 healthy volunteers. This study will compare the formulations employed in the phase 2b and phase 3 trials of roluperidone, as well as at least one new formulation to facilitate large scale manufacturing.

"The results of the open-label extension of the phase 3 trial with roluperidone provide additional support for the continued development of this agent, particularly in an environment with a continuing significant unmet medical need for schizophrenia treatments with novel mechanisms of action," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

"In addition, we have initiated the bioequivalence study and are simultaneously moving forward with activities that we believe are necessary to support the submission of a New Drug Application for roluperidone," said Dr. Luthringer.

First Quarter 2021 Financial Results

- **Net Loss:** Net loss was $8.8 million for the first quarter of 2021, or a loss per share of $0.21 (basic and diluted), compared to a net loss of $12.2 million for the first quarter of 2020, or a loss per share of $0.31 (basic and diluted).
- **R&D Expenses:** Research and development (R&D) expenses were $3.3 million and $8.1 million for the three months ended March 31, 2021 and 2020, respectively, a decrease of approximately $4.8 million. The decrease in R&D expenses was primarily due to lower costs for the Phase 3 clinical trial of roluperidone as a result of the completion in May 2020 of the three-month core study portion of the trial. Non-cash stock compensation expense included in R&D expenses was $0.6 million and $0.7 million for the three months ended March 31, 2021 and 2020, respectively.
- **G&A Expenses:** General and administrative (G&A) expenses were $4.2 million for both the three months ended March 31, 2021 and 2020. G&A expenses included compensation costs, consulting expenses, and insurance premiums. Non-cash stock compensation expense included in G&A expenses was $0.9 million and $1.5 million for the three months ended March 31, 2021 and 2020, respectively.
- **Cash Position:** Cash, cash equivalents, and restricted cash at March 31, 2021 were approximately $80.2 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 8981662.

The live webcast can be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at ir.minervaneurosciences.com. The archived webcast will be available on the website beginning approximately two hours after the event for 90 days.

About Minerva Neurosciences

Minerva's portfolio of compounds includes: roluperidone (MIN-101), in clinical development for schizophrenia, and MIN-301, in pre-clinical development for Parkinson's disease. Minerva's common stock is listed on the NASDAQ Global Market under the symbol "NERV." For more information, please visit www.minervaneurosciences.com.

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 statements herein with respect to the timing and scope of future clinical trials and results of clinical trials with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the likelihood of successful clinical trials, regulatory review, commercialization, and future sales of and potential royalty stream from seltorexant; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize our therapeutic products; 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 March 31, 2021, filed with the Securities and Exchange Commission on May 12, 2021. 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 disclaim any obligation to update any forward-looking statements, except as required by law.

CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	March 31, 2021	December 31, 2020
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 80,140	$ 25,357
Restricted cash	100	100
Prepaid expenses and other current assets	1,449	1,983
Total current assets	81,689	27,440
Other noncurrent assets	15	15
Operating lease right-of-use assets	59	102
In-process research and development	15,200	15,200
Goodwill	14,869	14,869
Total Assets	$ 111,832	$ 57,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,130	$ 996
Accrued expenses and other current liabilities	2,165	2,053
Operating leases	64	111
Total current liabilities	3,359	3,160
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Liability related to the sale of future royalties	61,296	-
Total liabilities	66,458	4,963
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	338,970	337,454
Accumulated deficit	(293,600)	(284,795)
Total stockholders' equity	45,374	52,663
Total Liabilities and Stockholders' Equity	$ 111,832	$ 57,626

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2021	2020

Collaborative revenue	$ -	$ -
Operating expenses:		
Research and development	3,259	8,083
General and administrative	4,249	4,189
Total operating expenses	7,508	12,272
Loss from operations	(7,508)	(12,272)
Foreign exchange losses	(5)	(9)
Investment income	4	130
Non-cash interest expense for the sale of future royalties	(1,296)	-
Loss before income taxes	(8,805)	(12,151)
Benefit for income taxes	-	-
Net loss	(8,805)	(12,151)
Net loss per share, basic and diluted	$ (0.21)	$ (0.31)
Weighted average shares outstanding, basic and diluted	42,722	39,178

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Source: Minerva Neurosciences, Inc