Minerva Neurosciences Reports First Quarter 2020 Financial Results and Business Updates

May 4, 2020

Top line results from pivotal Phase 3 trial with roluperidone in negative symptoms in patients diagnosed with schizophrenia on track for release in second quarter

WALTHAM, Mass., May 04, 2020 (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.

“We are pleased to report that we are approaching the conclusion of the double-blind, 12-week phase of our pivotal Phase 3 trial with roluperidone and reiterate our previous guidance that we expect to report top line results in the second quarter,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “Progress in this trial has been unaffected to date by the coronavirus pandemic and we are continually monitoring each trial site and our contract research organizations to ensure the safety of all patients and their access to study drug,” said Dr. Luthringer. “The last patient visit has taken place in the double-blind phase of the trial, in which a total of 515 patients were enrolled. In total, 362 patients have completed the double-blind phase, 333 patients from the double-blind phase have elected to transition into the open-label extension period, and 92 patients have completed the extension phase as of April 30, 2020.

“Finally, the prominent role of negative symptoms in schizophrenia has been increasingly highlighted by the key opinion leader (KOL) community since we initiated the Phase 3 trial,” said Dr. Luthringer. “Our recent KOL webcast, which included the participation of Dr. Stephen Marder, Dr. William Carpenter, Dr. Ofer Agid and Dr. John Kane, discussed how roluperidone may play an important role in treating the negative symptoms of schizophrenia, which persist and worsen over the lifetimes of the majority of patients, accounting for their functional disability and severely limiting their social and vocational reintegration over the long term.”

Clinical Development Updates

Roluperidone (MIN-101):

Following the completion of enrollment in a pivotal Phase 3 trial with roluperidone (clinicaltrials.gov identifier: NCT033971340) to treat negative symptoms in schizophrenia in February 2020, top-line results from this trial are expected in the second quarter of 2020, consistent with previous guidance. In parallel with completing this trial, the Company is advancing preparatory work for regulatory filing and commercialization, including clinical pharmacology studies, manufacturing of registration batches of the drug, medical affairs, commercialization strategy and product launch planning.

Seltorexant (MIN-202)

The Company and its co-development and co-commercialization partner, Janssen Pharmaceutica NV, met recently with the U.S. Food and Drug Administration (FDA) to discuss the Phase 3 program for seltorexant based on findings from trials with seltorexant completed in 2019. The two companies are consulting with each other and with the FDA and the European Medicines Agency/ Committee for Medicinal Products for Human Use about a target indication of adjunctive Major Depressive Disorder (aMDD) in patients with insomnia symptoms and clinical trials to support that target indication.

First Quarter 2020 Financial Results

- **Net Loss:** Net loss was $12.2 million for the first quarter of 2020, or a loss per share of $0.31 (basic and diluted), compared to a net loss of $15.8 million for the first quarter of 2019, or a loss per share of $0.41 (basic and diluted).

- **R&D Expenses:** Research and development (R&D) expenses were $8.1 million in the first quarter of 2020, compared to $11.6 million in the first quarter of 2019. The decrease in R&D expenses primarily reflects lower development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117. R&D expenses are expected to decrease during 2020 with the completion of the Phase 2b trial of MIN-117 and the 12-week, double-blind portion of the Phase 3 clinical trial of roluperidone.

- **G&A Expenses:** General and administrative (G&A) expenses were $4.2 million in the first quarter of 2020, compared to $4.7 million in the first quarter of 2019. This decrease in G&A expenses was primarily due to a decrease in non-cash stock-based compensation expenses and a decrease in professional fees.

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of March 31, 2020 were approximately $37.6 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 3969525.

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 proprietary compounds include: roluperidone (MIN-101), in clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and MDD; 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 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 statements herein with respect to the timing and scope of future clinical trials and results of clinical trials with roluperidone (MIN-101) and seltorexant (MIN-202); the clinical and therapeutic potential of these compounds; 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; management’s ability to successfully achieve its goals; and the impact of the coronavirus (COVID-19) pandemic. 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, seltorexant and MIN-301 will advance further in the clinical trials process and whether and when, if at all, they 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 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, 2020, filed with the Securities and Exchange Commission on May 4, 2020. 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, 2020	December 31, 2019
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 30,036	$ 21,413
Marketable securities	7,478	24,442
Restricted cash	100	100
Prepaid expenses and other current assets	852	1,182
Total current assets	38,466	47,137
Equipment, net	12	16
Other noncurrent assets	15	15
Operating lease right-of-use assets	224	262
In-process research and development	15,200	15,200
Goodwill	14,869	14,869
Total Assets	$ 68,786	$ 77,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,003	$ 2,317
Accrued expenses and other current liabilities	3,936	4,139
Operating leases	179	173
Total current liabilities	7,118	6,629
Long-Term Liabilities:		
Deferred taxes	1,803	1,803
Deferred revenue	41,176	41,176
Noncurrent operating leases	64	111
Total liabilities	50,161	49,719
Stockholders' Equity:		
Common stock	4	4

Additional paid-in capital	317,508	314,512
Accumulated deficit	(298,887)	(286,736)
Total stockholders' equity	18,625	27,780
Total Liabilities and Stockholders' Equity	$ 68,786	$ 77,499

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2020	**2019**
Revenues	$ -	$ -
Operating expenses:		
Research and development	8,083	11,606
General and administrative	4,189	4,706
Total operating expenses	12,272	16,312
Foreign exchange losses	(9)	(6)
Investment income	130	491
Net (loss) income	$ (12,151)	$ (15,827)
Loss per share:		
Basic and diluted	$ (0.31)	$ (0.41)
Weighted average shares:		
Basic and diluted	39,178	38,968

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