Minerva Neurosciences Reports First Quarter 2018 Financial Results and Business Updates

May 3, 2018

WALTHAM, Mass., May 03, 2018 (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, 2018.

“Minerva now has five late-stage clinical efficacy trials ongoing with three compounds,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “These include our lead product, roluperidone (MIN-101) for schizophrenia, MIN-117 for MDD and seltorexant (MIN-202) for insomnia disorder and MDD.

“In schizophrenia, the leading unmet medical need as ranked by psychiatrists is negative symptoms, the target indication for roluperidone,” said Dr. Luthringer. “Based on the improvement in negative symptoms measured in clinical tests with roluperidone to date, combined with the observed stability in positive symptoms and a favorable side effect profile, we believe this compound has the potential to be a differentiated therapy in schizophrenia, and we are working on commercialization strategies that address this significant commercial opportunity.”

Clinical Development Updates

Roluperidone (MIN-101):

- The Company’s clinical sites in the U.S. are actively enrolling patients in the pivotal Phase 3 trial with roluperidone. The Company has prioritized the initiation of U.S. sites, and now European sites have been initiated. Target enrollment in this trial is approximately 500 patients. Top-line results are expected in the first half of 2019.

MIN-117:

- As announced on April 9, 2018, the Company has enrolled the first patient in a Phase 2b trial of MIN-117 to treat the symptoms of patients diagnosed with MDD. Approximately 324 patients will be enrolled at clinical sites in the U.S. and Europe. Top-line results are expected in the first half of 2019.

Seltorexant (MIN-202 or JNJ-42847922), under joint development with Janssen Pharmaceutica NV (Janssen):

- Three Phase 2b clinical trials are ongoing with seltorexant, including two in MDD and one in insomnia disorder. In the first MDD trial, approximately 280 patients are planned to be enrolled at clinical sites in the U.S., Europe and Japan. In the second MDD trial, approximately 100 patients are planned to be randomized at clinical sites in the U.S. The insomnia trial is expected to enroll a total of approximately 360 patients at clinical sites in the U.S., Europe and Japan. These trials are planned for completion in 2019.

First Quarter 2018 Financial Results

- **Net Loss:** Net loss was $12.4 million for the first quarter of 2018, or a loss per share of $0.32 (basic and diluted), compared to a net loss of $10.6 million for the first quarter of 2017, or a loss per share of $0.30 (basic and diluted).

- **R&D Expenses:** Research and development (R&D) expenses were $8.4 million in the first quarter of 2018, compared to $7.6 million in the first quarter of 2017. The increase in R&D expenses primarily reflects higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117. These amounts were partially offset by lower development expenses for the seltorexant program due to the amendment to the Company’s Co-Development and License Agreement with Janssen. R&D expenses are expected to increase during 2018 with increased patient enrollment and related support activities for the roluperidone and MIN-117 clinical trials.

- **G&A Expenses:** General and administrative (G&A) expenses were $4.3 million in the first quarter of 2018, compared to $2.9 million in the first quarter of 2017. This increase in G&A expenses was primarily due to an increase in non-cash stock-based compensation expenses and salary costs from increased staffing to support the Company's pre-commerical activities. G&A expenses are expected to increase during 2018 with investment in the infrastructure necessary to support the Company’s growth.

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of March 31, 2018 were approximately $121.1 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 8885379.

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 Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat CNS diseases. Minerva’s proprietary compounds include: roluperidone (MIN-101), in clinical development for schizophrenia; MIN-117, in clinical development for major depressive disorder (MDD); 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 current clinical trials and results of clinical trials with roluperidone, seltorexant, MIN-117 and MIN-301; the timing and scope of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these compounds; 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, seltorexant, MIN-117 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 Annual Report on Form 10-Q for the quarter ended March 31, 2018, filed with the Securities and Exchange Commission on May 3, 2018. 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, 2018	December 31, 2017
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 45,126	$ 26,052
Marketable securities	75,871	102,109
Restricted cash	100	80
Prepaid expenses and other current assets	4,243	1,299
Total current assets	125,340	129,540
Marketable securities - noncurrent	-	5,023
Equipment, net	47	51
Other noncurrent assets	15	15
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 174,471	$ 183,698
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable	$ 2,697	$ 3,962
Accounts payable	2,825	1,436
Accrued expenses and other current liabilities	2,393	1,439
Total current liabilities	7,915	6,837
Long-Term Liabilities:		
Deferred taxes	4,057	4,057
Deferred revenue	41,176	41,176
Other noncurrent liabilities	30	30
Total liabilities	53,178	52,100
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	298,089	295,975

Accumulated deficit	(176,800)	(164,381)
Total stockholders' equity	121,293	131,598
Total Liabilities and Stockholders' Equity	$ 174,471	$ 183,698

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2018	**2017**
Revenues	$ -	$ -
Operating expenses:		
Research and development	8,449	7,614
General and administrative	4,294	2,871
Total operating expenses	12,743	10,485
Foreign exchange losses	(18)	(17)
Investment income	414	59
Interest expense	(71)	(202)
Net income (loss)	$ (12,418)	$ (10,645)
Loss per share:		
Basic and diluted	$ (0.32)	$ (0.30)
Weighted average shares:		
Basic and diluted	38,749	35,370

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Source: Minerva Neurosciences, Inc