May 4, 2017

Minerva Neurosciences Reports First Quarter 2017 Financial Results and Business Updates

WALTHAM, Mass., May 04, 2017 (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, 2017.

"We recently had a meeting with the U.S. Food and Drug Administration (FDA) to obtain feedback and guidance related to the Phase III clinical development of MIN-101 as a treatment for negative symptoms of schizophrenia," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "We expect to initiate Phase III development of this compound in the second half of 2017."

Clinical Development Updates

MIN-101:

- An "end-of-Phase II meeting" with the FDA took place recently to review pre-clinical and clinical data generated to date with MIN-101 and to discuss Phase III and Phase IV clinical development of this compound to treat negative symptoms in patients with a diagnosis of schizophrenia, including pivotal trial design.

MIN-117:

- Following the acceptance of the Investigational New Drug application (IND) for MIN-117 by the FDA late last year, Minerva is planning clinical trials with this compound in the U.S. and Europe. These trials will build upon the results from the Phase IIa trial with MIN-117, and they are expected to begin in late 2017.

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

- The planned indications for the next stage of clinical development with MIN-202 include insomnia without neuro-psychiatric comorbid symptoms and comorbid insomnia in patients suffering from depressive disorders. A number of supportive activities and clinical pharmacology studies are being conducted by Minerva and Janssen in preparation for trials in both indications.

First Quarter 2017 Financial Results

- **Net Loss:** Net loss was $10.6 million for the first quarter of 2017, or a loss per share of $0.30 (basic and diluted), compared to a net loss of $8.0 million, or a loss per share of $0.29 (basic and diluted) for the first quarter of 2016.

- **R&D Expenses:** Research and development (R&D) expenses were $7.6 million in the first quarter of 2017, compared to $5.4 million in the first quarter of 2016. R&D expense in the three month periods ended March 31, 2017 and 2016 included non-cash stock based compensation expenses of $0.5 million and $0.2 million, respectively. This increase in R&D expenses primarily reflects higher development expenses under the MIN-202 program for Phase II clinical trial preparation and an increase in non-cash, stock-based compensation expenses. These amounts were partially offset by lower costs due to the completion of our Phase IIb clinical trial of MIN-101 and the completion of our Phase IIa clinical trial of MIN-117.

- **G&A Expenses:** General and administrative (G&A) expenses were $2.9 million in the first quarter of 2017, compared to $2.4 million in the first quarter of 2016. G&A expense in the three month periods ended March 31, 2017 and 2016 included non-cash stock-based compensation expenses of $0.8 million and $0.6 million, respectively. This increase in general and administrative expenses was primarily due to an increase in legal and professional fees, an increase in non-cash stock-based compensation expenses, and increased personnel costs during the three months ended March 31, 2017.

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2017 were approximately $85.4 million. The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to meet its cash commitments for at least the next 12 months.

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 2971783.

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: MIN-101, in clinical development for schizophrenia; MIN-117, in clinical development for major depressive disorder (MDD); MIN-202 (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 results of future clinical milestones with MIN-101, MIN-202 and MIN-117, including the planned Phase III trial of MIN-101, the timing and scope of future clinical trials and results of clinical trials with 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; 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 any of our therapeutic products 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 the results of future clinical trials of any of our therapeutic products, if any, will be consistent with the results of past clinical trials; 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; our ability to achieve the results contemplated by our co-development agreements; 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, 2017, filed with the Securities and Exchange Commission on May 4, 2017. 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, 2017	December 31, 2016
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 68,895	$ 82,981
Marketable securities	16,465	-
Restricted cash	80	80
Prepaid expenses and other current assets	792	803
Total current assets	86,232	83,864
Equipment, net	6	10
In-process research and development	34,200	34,200

Goodwill	14,869	14,869
Total Assets	$ 135,307	$ 132,943

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Notes payable - current portion	$ 4,959	$ 4,854
Accounts payable	3,276	1,467
Accrued expenses and other current liabilities	1,673	816
Accrued collaborative expenses	3,078	2,548
Total current liabilities	12,986	9,685
Long-Term Liabilities:		
Notes payable - noncurrent	2,601	3,841
Deferred taxes	13,434	13,434
Total liabilities	29,021	26,960
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	249,785	238,837
Accumulated deficit	(143,503)	(132,858)
Total stockholders' equity	106,286	105,983
Total Liabilities and Stockholders' Equity	$ 135,307	$ 132,943

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, (in thousands, except per share amounts)	
	2017	**2016**
Revenues	$ -	$ -
Operating expenses:		
Research and development	7,614	5,375
General and administrative	2,871	2,382
Total operating expenses	10,485	7,757
Foreign exchange losses	(17)	(9)
Investment income	59	32
Interest expense	(202)	(270)
Net loss	$ (10,645)	$ (8,004)
Loss per share:		
Basic and diluted	$ (0.30)	$ (0.29)
Weighted average shares:		
Basic and diluted	35,370	27,203

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Primary Logo

Source: Minerva Neurosciences, Inc.