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Minerva Neurosciences Reports First Quarter 2016 Financial Results and Business Updates

Positive top line results of trials with MIN-202 highlight first quarter

Last patient visits completed in trials with MIN-101 and MIN-117;

data expected in second quarter

WALTHAM, Mass., May 03, 2016 (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, 2016.

"The first quarter of 2016 was highlighted by positive top line results from two clinical trials with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "These include positive findings from a Phase IIa trial in insomnia disorder and a Phase Ib trial in patients diagnosed with a major depressive disorder (MDD) that pave the way toward the next steps in the clinical development of this product.

"We remain on schedule in the final stages of our ongoing Phase IIb trial in schizophrenia with MIN-101 and our ongoing Phase IIa trial with MIN-117 in MDD," said Dr. Luthringer. "Both trials recently reported last patient visits. Top line results from both trials are expected later in this quarter. Our objective for these trials is to support the potential of MIN-101 and MIN-117 to address significant unmet needs in the treatment of large numbers of patients with these diseases."

Clinical Trial Updates

MIN-101:

- A total of 244 patients have been enrolled in the Phase IIb, double-blind, placebo-controlled trial testing MIN-101, a first-in-class 5-HT_{2a} and sigma₂ antagonist for the treatment of schizophrenia. The primary objective of this trial is to evaluate the efficacy of MIN-101 given at once-a-day doses of 32 and 64 milligrams (mg) in the morning compared to placebo in improving the negative symptoms of schizophrenic patients over 12 weeks of treatment, as measured by the change from baseline in the Positive and Negative Syndrome Scale (PANSS) negative subscale score of the pentagonal model. Secondary objectives include assessment of the effect of MIN-101 on the total PANSS score and sub-scores, cognition and sleep. Safety and tolerability are also being monitored. Top line results for the core 12-week treatment evaluation period are expected in the second quarter of 2016. Patients who responded positively to treatment during the core 12-week double-blind period of the trial had the opportunity to enter an extension period of six months during which all patients receive either 32 mg or 64 mg of MIN-101. Patients who received placebo during the core study period of the trial were randomized to one of these two doses. The extension period is ongoing and expected to be completed during the third quarter of 2016.

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

- MIN-202, a selective orexin-2 receptor antagonist, has been evaluated in three recently completed clinical trials, including a Phase IIa trial in insomnia disorder conducted in the U.S. and Europe, a Phase Ib trial in patients suffering from MDD conducted in Europe, and a Phase I trial in healthy Japanese men.
- The Phase IIa trial in patients with insomnia disorder without psychiatric comorbidity was a randomized, placebo-controlled double-blind, two way cross-over study to evaluate treatment with MIN-202 (40 mg daily given in the evening for five consecutive days) versus placebo in 28 study participants. Patients treated with MIN-202 were observed to have statistically significant improvements, as compared to placebo, in all key sleep parameters assessing sleep induction and sleep maintenance. These parameters, measured by objective polysomnography, include sleep efficiency (SE), the primary endpoint of the trial, for which a positive and statistically significant efficacy signal was detected versus placebo ($p < 0.001$). Additional statistically significant positive efficacy signals were observed for key secondary parameters, including latency to persistent sleep (LPS), wake after sleep onset (WASO), and total sleep time (TST). MIN-202 did not affect deep sleep, an important sleep stage involved in physiological functions such as memory consolidation. Compared to placebo, MIN-202 was observed to significantly improve

polysomnography parameters ($p < 0.001$) on Days 1 and 5. Objective and subjective evaluations were significantly correlated. No serious adverse events were observed in this trial, and preliminary data indicate that MIN-202 was well tolerated by patients.

- | The Phase Ib trial was a randomized, double-blind, parallel group study including 20 mg of MIN-202 administered in the evening, a positive control, 25 mg of diphenhydramine, and placebo, to evaluate treatment with MIN-202 in 48 subjects ages 18 to 65 years with a diagnosis of MDD who could be treated with marketed antidepressants. The treatment duration was one month. Safety and tolerability, as well as effects on mood, cognition and stress hormone levels, were assessed. Consistently greater improvements in depressive symptomatology were observed in patients randomized to receive MIN-202 compared to those randomized to receive placebo or diphenhydramine, as measured by clinician administered rating scales, including the Hamilton Depression Rating Scale (HDRS₁₇). These findings support the potential of MIN-202 to have a direct effect on mood independent from its effect on sleep. MIN-202 was observed to be well tolerated by study participants over a one-month treatment duration, with no new emerging safety signals and no serious adverse events.
- | The Phase I trial in 24 healthy Japanese adult male study participants was a single-center, double-blind, placebo-controlled, randomized single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MIN-202. It was observed that single dose morning administration of MIN-202 was well tolerated at 5 mg, 20 mg and 40 mg. The observed plasma pharmacokinetic features were comparable to those observed in previous studies carried out in healthy non-Asian study participants. These findings expand the database of study participants treated with MIN-202 worldwide and support further clinical testing in an important part of the world.

MIN-117:

- | A total of 84 patients have been enrolled in the Phase IIa, double-blind, parallel group design, placebo- and active-controlled clinical trial in Europe of MIN-117, a compound that targets multiple receptors known to be involved in mood disorders. The trial includes four treatment arms, 0.5 mg and 2.5 mg daily of MIN-117, placebo and 20 mg daily of paroxetine. The primary endpoint is to evaluate the efficacy of MIN-117 versus placebo in reducing the symptoms of a major depressive episode as measured by the Montgomery-Asberg Depression Rating Scale over six weeks of treatment. Secondary endpoints include assessments of onset of mood improvement, cognition, sexual function and sleep. Safety and tolerability are also being monitored. Top line results are expected in the second quarter of 2016.

First Quarter 2016 Financial Results

- | **Net Loss:** Net loss was \$8.0 million for the first quarter of 2016, or a loss per share of \$0.29 (basic and diluted), compared to a net loss of \$6.1 million, or a loss per share of \$0.31 (basic and diluted) for the same period in 2015.
- | **R&D Expenses:** Research and development (R&D) expenses were \$5.4 million in the first quarter of 2016, compared to \$4.0 million in the first quarter of 2015. Research and development expense in the three month periods ended March 31, 2016 and 2015 included non-cash stock-based compensation expenses of \$0.2 million and \$0.1 million, respectively. Excluding stock-based compensation, total research and development expense related to drug development programs for the three months ended March 31, 2016 and 2015 was \$5.2 million and \$3.9 million, respectively. This increase in research and development expense primarily reflects increased expenses related to our Phase IIb clinical trial of MIN-101 and our Phase IIa clinical trial of MIN-117.
- | **G&A Expenses:** General and administrative (G&A) expenses were \$2.4 million in the first quarter of 2016, compared to \$1.9 million in the first quarter of 2015. General and administrative expense in the three month periods ended March 31, 2016 and 2015 included non-cash stock-based compensation expenses of \$0.6 million and \$0.3 million, respectively. Excluding stock-based compensation, general and administrative expense for the three months ended March 31, 2016 and 2015 was \$1.8 million and \$1.6 million, respectively.
- | **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2016 were approximately \$44.6 million. In the first quarter of 2016, the Company received approximately \$17.5 million in proceeds from the exercise by certain existing stockholders of warrants granted in connection with a private placement in March 2015. Warrants with respect to a total of 3,039,514 shares of common stock were exercised at an exercise price of \$5.77 per share. Also during the first quarter, the Company entered into a common stock purchase agreement with Dr. David Kupfer, a director, under which the Company sold to Dr. Kupfer 181,488 shares of the Company's stock at a price per share of \$5.51, for gross proceeds of approximately \$1 million. The Company anticipates that its cash, cash equivalents and marketable securities as of March 31, 2016 will be sufficient to fund its operations into the second quarter of 2017.

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 74086869.

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 products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, in Phase IIb development for schizophrenia; MIN-202 (JNJ-42847922), which recently completed Phase IIa and Phase Ib clinical trials for insomnia and major depressive disorder (MDD), respectively; MIN-117, in Phase IIa development for 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 and pre-clinical milestones with MIN-101, MIN-202, MIN-117 and MIN-301; the timing 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 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 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, 2016, filed with the Securities and Exchange Commission on May 3, 2016. 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,	December 31,
	2016	2015
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 34,822	\$ 14,284
Marketable securities	9,818	17,921
Restricted cash	80	80
Prepaid expenses	618	1,196
Total current assets	<u>45,338</u>	<u>33,481</u>
Equipment, net	22	26
In-process research and development	34,200	34,200
Goodwill	14,869	14,869

Total Assets	\$ 94,429	\$ 82,576
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LIABILITIES AND STOCKHOLDERS' DEFICIT

Current Liabilities:

Notes payable - current portion	\$ 2,644	\$ 1,435
Accounts payable	1,224	1,360
Accrued expenses and other current liabilities	3,101	2,525
Total current liabilities	<u>6,969</u>	<u>5,320</u>

Long-Term Liabilities:

Notes payable - noncurrent	7,376	8,503
Deferred taxes	13,434	13,434
Total liabilities	<u>27,779</u>	<u>27,257</u>

Stockholders' Deficit:

Common stock	3	2
Additional paid-in capital	176,464	157,130
Accumulated deficit	(109,817)	(101,813)
Total stockholders' deficit	<u>66,650</u>	<u>55,319</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 94,429</u>	<u>\$ 82,576</u>

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	<u>2016</u>	<u>2015</u>
Revenues	\$ -	\$ -
Operating expenses:		
Research and development	5,375	3,961
General and administrative	2,382	1,917
Total operating expenses	<u>7,757</u>	<u>5,878</u>
Foreign exchange (losses)/gains	(9)	16
Investment income	32	-
Interest expense	(270)	(231)
Net loss	<u>\$ (8,004)</u>	<u>\$ (6,093)</u>
Loss per share:		
Basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.31)</u>
Weighted average shares:		
Basic and diluted	<u>27,203</u>	<u>19,417</u>

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