



November 3, 2016

Minerva Neurosciences Reports Third Quarter 2016 Financial Results and Business Updates

Management to host conference call today at 8:30 a.m. Eastern Time

WALTHAM, Mass., Nov. 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 third quarter ended September 30, 2016.

"Recent highlights for Minerva include the completion and analyses of positive data from the 24-week open label extension phase of our Phase IIb trial with MIN-101 for schizophrenia announced on October 26 and the acceptance of four abstracts for presentation at the 55th Annual Meeting of the American College of Neuropsychopharmacology (ACNP), including a featured oral presentation of data from the MIN-101 trial," said Dr. Remy Luthringer, president and chief executive officer of Minerva.

"Combined with the statistically significant data from the randomized, double-blind, placebo-controlled 12-week core phase of the Phase IIb trial announced earlier this year, the extension data help shape the Phase III clinical strategy with MIN-101 as a differentiated treatment for schizophrenia patients with negative symptoms," said Dr. Luthringer. "With these data in hand, we intend to meet with the U.S. Food and Drug Administration (FDA) to determine the late stage clinical strategy and more specifically the design of the next clinical trials with MIN-101. Our objective is to initiate these trials in mid-2017."

MIN-101:

- | Data from the extension of the Phase IIb trial with MIN-101 demonstrate a further and continuous improvement in negative symptoms in patients with schizophrenia, as measured by the negative symptoms subscales of the Positive and Negative Syndrome Scale (PANSS). Based on the PANSS pentagonal structure model (PSM), negative symptoms were observed to continue to improve during the extension phase, with a reduction from the start of the study for the 32 and 64 milligram (mg) MIN-101-treated groups of 5.5 points and 4.9 points, respectively. Based on the PANSS three factors negative symptoms subscale, negative symptoms were also observed to continue to improve, with a reduction of 5.4 points and 5.3 points, respectively.
- | Positive symptoms were observed to remain stable throughout the study, as measured by PANSS positive symptom scores.
- | MIN-101 was generally reported to be well tolerated through the entire 36-week period. QTcF, a measurement of cardiac function, was closely monitored throughout the study, and discontinuation criteria based on QTcF prolongation were incorporated in the protocol. As previously announced, two patients out of 162 who received MIN-101 in the core phase were discontinued based upon these criteria; both of these patients received the higher dose (64 mg). In the extension phase no additional patients were discontinued. The extension data also confirm that MIN-101 at the doses tested did not have an effect on extra-pyramidal symptoms (EPS), prolactin or weight.

MIN-117:

- | The FDA has accepted the Company's Investigational New Drug (IND) application for MIN-117. FDA acceptance of this IND allows us to begin clinical trials with this compound in the United States, building upon the positive results of the Company's Phase IIa trial in Europe announced earlier this year.
- | The Company is evaluating its next steps in the development of MIN-117 as a treatment for MDD based on its potential differentiation from existing therapies, including the potential for early onset, efficacy on symptoms of both MDD and anxiety, lack of impairment in cognition and sexual function, and preservation of sleep architecture and continuity.

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

- | Minerva and its co-development partner for MIN-202, Janssen, are conducting a number of supportive activities in anticipation of the next phase of clinical trials in insomnia disorder and major depressive disorder, which are anticipated to begin in early 2017.

MIN-301:

- | The Company is pursuing the pre-clinical development of MIN-301, a peptide which targets the extra-cellular domain of neuregulin-1 beta-1 activating ErbB4. The next planned steps in this program are the filing of an Investigational New Drug application in the United States or an Investigational Medicinal Product Dossier in Europe, and pending acceptance by regulatory authorities, the initiation of Phase I clinical testing thereafter.

Third Quarter 2016 Financial Results

- | **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2016 were approximately \$91.9 million, compared to \$32.2 million as of December 31, 2015. As previously stated, Minerva expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operations into 2018.
- | **R&D Expenses:** Research and development (R&D) expenses were \$5.9 million in the third quarter of 2016, compared to \$3.8 million in the third quarter of 2015. For the nine months ended September 30, 2016, R&D expenses were \$13.9 million, compared to \$12.3 million for the nine months ended September 30, 2015.

Excluding stock-based compensation, total research and development expense related to drug development programs for the three months ended September 30, 2016 and 2015 was \$5.6 million and \$3.6 million, respectively, an increase of \$2.0 million. This increase in research and development expenses primarily reflects higher development expenses under the MIN-202 program for Phase II clinical trial preparation, partially offset by lower costs for our MIN-101 and MIN-117 programs as those clinical trials have concluded.

Excluding stock-based compensation, total research and development expense related to drug development programs for the nine months ended September 30, 2016 and 2015 was \$13.2 million and \$11.9 million, respectively, an increase of \$1.3 million. This increase in research and development expenses primarily reflects higher development expenses under the MIN-202 program for Phase II clinical trial preparation, increased expenses related to our Phase IIa clinical trial of MIN-117 and increased expenses related to our MIN-301 development. This was partially offset by decreased expenses due to the completion of our Phase IIb clinical trial of MIN-101.

- | **G&A Expenses:** General and administrative (G&A) expenses were \$2.4 million in the third quarter of 2016, compared to \$1.9 million in the third quarter of 2015. For the nine months ended September 30, 2016, G&A expenses were \$7.0 million, compared to \$5.6 million for the same period in 2015.

General and administrative expense in the three months ended September 30, 2016 and 2015 included non-cash stock-based compensation expenses of \$0.7 million and \$0.4 million, respectively. Excluding stock-based compensation, general and administrative expense for the three months ended September 30, 2016 and 2015 was \$1.7 million and \$1.5 million, respectively. This increase was primarily due to an increase in professional fees during the three months ended September 30, 2016.

General and administrative expense in the nine months ended September 30, 2016 and 2015 included non-cash stock-based compensation expenses of \$1.8 million and \$1.1 million, respectively. Excluding stock-based compensation, general and administrative expense for the nine months ended September 30, 2016 and 2015 was \$5.2 million and \$4.5 million, respectively. This increase was primarily due to an increase in personnel costs and professional fees during the nine months ended September 30, 2016.

- | **Net Loss:** Net loss was \$8.4 million for the third quarter of 2016, or a loss per share of \$0.24 (basic and diluted), as compared to a net loss of \$5.9 million, or a loss per share of \$0.24 (basic and diluted) for the third quarter of 2015. Net loss was \$21.6 million for the first nine months of 2016, or a loss per share of \$0.71 (basic and diluted), as compared to a net loss of \$18.6 million, or a loss per share of \$0.81 (basic and diluted) for the first nine months of 2015.

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 90389179.

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, which has completed a Phase IIb clinical trial for schizophrenia; MIN-117, which has completed a Phase IIa clinical trial development for MDD; MIN-202 (JNJ-42847922), which has completed Phase IIa and Phase Ib clinical trials for insomnia and MDD, respectively; 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 September 30, 2016, filed with the Securities and Exchange Commission on November 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)

	September 30, December 31,	
	2016	2015
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 91,853	\$ 14,284
Marketable securities	-	17,921
Restricted cash	80	80
Prepaid expenses and other current assets	703	1,196
Total current assets	<u>92,636</u>	<u>33,481</u>
Equipment, net	13	26
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	<u>\$ 141,718</u>	<u>\$ 82,576</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Notes payable - current portion	\$ 4,751	\$ 1,435
Accounts payable	832	1,360
Accrued expenses and other current liabilities	981	2,525
Accrued collaborative expenses	3,534	-
Total current liabilities	<u>10,098</u>	<u>5,320</u>
Long-Term Liabilities:		
Notes payable - noncurrent	5,049	8,503
Deferred taxes	13,434	13,434
Total liabilities	<u>28,581</u>	<u>27,257</u>
Stockholders' Equity:		
Common stock	3	2
Additional paid-in capital	236,588	157,130

Accumulated deficit	(123,454)	(101,813)
Total stockholders' equity	113,137	55,319
Total Liabilities and Stockholders' Equity	\$ 141,718	\$ 82,576

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	(in thousands, except per share amounts)		(in thousands, except per share amounts)	
	2016	2015	2016	2015
Revenues	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	5,852	3,828	13,941	12,274
General and administrative	2,380	1,877	7,012	5,641
Total operating expenses	8,232	5,705	20,953	17,915
Foreign exchange losses	(3)	(2)	(28)	(15)
Investment income	70	38	137	64
Interest expense	(259)	(270)	(797)	(776)
Net loss	\$ (8,424)	\$ (5,939)	\$ (21,641)	\$ (18,642)
Loss per share:				
Basic and diluted	\$ (0.24)	\$ (0.24)	\$ (0.71)	\$ (0.81)
Weighted average shares:				
Basic and diluted	34,806	24,721	30,393	22,972

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