



November 5, 2015

## Minerva Neurosciences Reports Third Quarter 2015 Financial Results and Business Updates

### Clinical Trials Remain on Track for Data Readouts in the First Half of 2016

#### Dr. David Kupfer Joins Board of Directors

#### Management to Host Conference Call Today at 8:30 a.m. Eastern Time

WALTHAM, Mass., Nov. 5, 2015 (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, 2015.

"Patient recruitment in ongoing trials with Minerva's three clinical-stage compounds is leading toward a number of data milestones expected to occur during the first half of 2016," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "These trials include the Phase IIb trial with MIN-101 in schizophrenia, the Phase IIa trial with MIN-202 in insomnia disorder, the Phase Ib trial with MIN-202 in adjunctive major depressive disorder (MDD) and the Phase IIa trial with MIN-117 in MDD. Data generated from these trials will inform our decisions about the next stage of clinical development for each product candidate."

#### MIN-101:

- The recruitment of schizophrenic patients with a history of negative symptoms in the ongoing Phase IIb study in Europe is expected to continue through the end of 2015. The target recruitment goal is 234 patients, with one third of those patients receiving a dose of 32 milligrams (mg) daily, one third 64 mg daily and one third on placebo. The primary study objective is an evaluation of the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenia. Topline results for the core 12-week evaluation period are expected in the second quarter of 2016.

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

- Patients are being recruited in two trials with MIN-202 conducted by Janssen, including a Phase IIa trial in insomnia disorder and a Phase Ib trial in adjunctive MDD. The Phase IIa trial is a randomized, placebo-controlled double-blind study to evaluate treatment with MIN-202 in 26 subjects with insomnia disorder without psychiatric co-morbidity. The primary endpoint of this trial is sleep efficiency as measured by polysomnography, and secondary endpoints include additional assessments of sleep, mood and cognition, as well as safety. The trial is being conducted at clinical sites in the U.S. and Europe, and the data readout is expected in the first half of 2016.
- The Phase Ib trial is a randomized, diphenhydramine- and placebo-controlled double-blind study to evaluate treatment with MIN-202 in 48 subjects with MDD. Patients will be enrolled in three groups, which will be treated with MIN-202, diphenhydramine and placebo, respectively, while maintained on their antidepressant regimens. The primary endpoint of this trial is safety, and secondary endpoints include assessments of depressive symptomology, cognition and sleep. The trial is being conducted at clinical sites in Europe, and the data readout is expected in the first half of 2016.

#### MIN-117:

- Patient recruitment is ongoing in a Phase IIa clinical trial of MIN-117 in patients with MDD. The target patient recruitment goal is 80 patients, of whom 20 will receive a 0.5 mg dose of MIN-117 daily, 20 will receive a 2.5 mg dose of MIN-117 daily, 20 will receive a 20 mg dose of paroxetine daily and 20 will receive placebo. The primary endpoint of the trial will be the efficacy of MIN-117 versus placebo in reducing depressive symptoms. Top-line results are expected in the first half of 2016.

#### MIN-301:

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

## Board of Directors:

- David J. Kupfer, M.D. has been appointed to Minerva's board of directors, effective November 2, 2015. An international leader in psychiatry and psychiatric research, he chaired the American Psychiatric Association Task Force for the development of the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), which defines the criteria for the diagnosis and classification of mental disorders. Dr. Kupfer received his M.D. from Yale University in 1965. He is Distinguished Professor emeritus of Psychiatry at the University of Pittsburgh School of Medicine, where he chaired that department for 26 years. As director of research at Western Psychiatric Institute and Clinic (WPIC), Dr. Kupfer helped establish WPIC as one of the nation's preeminent university-based psychiatric research centers. He is founding president of the International Society of Bipolar Disorders and was elected to the National Academy of Medicine (formerly the Institute of Medicine) in 1990.

## Third Quarter 2015 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities (current and non-current) as of September 30, 2015 were approximately \$38.9 million, compared to \$18.5 million as of December 31, 2014. As previously stated, Minerva expects that its cash, cash equivalents and marketable securities (current and non-current) will be sufficient to fund its operations into the fourth quarter of 2016.
- **R&D Expenses:** Research and development (R&D) expenses were \$3.8 million in the third quarter of 2015, compared to \$24.7 million in the third quarter of 2014. For the nine months ended September 30, 2015, R&D expenses were \$12.3 million, compared to \$39.9 million for the nine months ended September 30, 2014. R&D expenses in the three and nine months ended September 30, 2014 included a \$22.0 million license fee paid to Janssen pursuant to the Company's co-development agreement for MIN-202. R&D expenses in the nine months ended September 30, 2015 and 2014 included non-cash stock-based compensation expenses of \$0.4 million and \$13.0 million, respectively. Excluding stock-based compensation and the \$22.0 million license fee, R&D expenses for the Company's drug development programs for the three and nine months ended September 30, 2015 totaled \$3.6 million and \$11.9 million, respectively, versus \$2.6 million and \$4.9 million in the prior year period. These increases over the prior year in R&D expenses for the Company's drug development programs for the three and nine months ended September 30, 2015 of \$1.0 million and \$7.0 million, respectively, primarily reflect increased expenses related to the Phase IIb clinical trial of MIN-101, the Phase IIa trial of MIN-117 and the recent MIN-202 clinical trials.
- **G&A Expenses:** General and administrative (G&A) expenses were \$1.9 million in the third quarter of 2015, compared to \$2.4 million in the third quarter of 2014. For the nine months ended September 30, 2015, G&A expenses were \$5.6 million, compared to \$7.5 million for the same period in 2014. The decreases in G&A expenses for the three and nine months ended September 30, 2015 over the same periods in 2014 were primarily due to a decrease in non-cash stock-based compensation expense of \$0.4 million and \$1.6 million, respectively.
- **Net Loss:** Net loss was \$5.9 million for the third quarter of 2015, or a loss per share of \$0.24 (basic and diluted), as compared to a net loss of \$27.2 million, or a loss per share of \$1.53 (basic and diluted) for the third quarter of 2014. Net loss was \$18.6 million for the first nine months of 2015, or a loss per share of \$0.81 (basic and diluted), as compared to a net loss of \$49.5 million, or a loss per share of \$4.58 (basic and diluted) for the first nine months of 2014.

## 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 56415971.

The live webcast can be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at [ir.minervaneurosciences.com](http://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), in Phase IIa and Phase Ib development for insomnia and adjunctive major depressive disorder (MDD), respectively; MIN-117, in development for MDD; and MIN-301, in pre-clinical development for the treatment of 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](http://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; the timing of future clinical trials and results of clinical trials; the clinical and therapeutic potential of our 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 other 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, 2015, filed with the Securities and Exchange Commission on November 5, 2015. Copies of reports filed with the SEC are posted on our website at [www.minervaneurosciences.com](http://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

(Unaudited)

	September 30, 2015	December 31, 2014
	(in thousands)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 16,837	\$ 18,546
Marketable securities - current portion	20,651	--
Restricted cash	80	35
Prepaid expenses	1,243	757
Total current assets	<u>38,811</u>	<u>19,338</u>
Marketable securities - noncurrent	1,407	--
Equipment, net	31	44
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	<u>\$ 89,318</u>	<u>\$ 68,451</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Notes payable - current portion	\$ 252	\$ --
Accounts payable	735	642
Accrued expenses and other current liabilities	2,225	1,645
Accrued collaborative expenses	--	1,222
Total current liabilities	<u>3,212</u>	<u>3,509</u>
Long-Term Liabilities:		
Notes payable - noncurrent	9,606	--
Deferred taxes	13,434	13,434
Other non-current liabilities	--	8
Total liabilities	<u>26,252</u>	<u>16,951</u>
Stockholders' Equity:		
Common stock	2	2
Additional paid-in capital	156,438	126,229

Accumulated deficit	<u>(93,374)</u>	<u>(74,731)</u>
Total stockholders' equity	<u>63,066</u>	<u>51,500</u>
Total Liabilities and Stockholders' Equity	<u>\$ 89,318</u>	<u>\$ 68,451</u>

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2015	2014	2015	2014
Revenues	\$ --	\$ --	\$ --	\$ --
Operating expenses:				
Research and development	3,828	24,738	12,274	39,940
General and administrative	<u>1,877</u>	<u>2,413</u>	<u>5,641</u>	<u>7,485</u>
Total operating expenses	<u>5,705</u>	<u>27,151</u>	<u>17,915</u>	<u>47,425</u>
Loss from operations	(5,705)	(27,151)	(17,915)	(47,425)
Foreign exchange (losses)/gains	(2)	11	(15)	15
Investment income	38	--	64	--
Interest expense	<u>(270)</u>	<u>(15)</u>	<u>(776)</u>	<u>(2,049)</u>
Net loss	<u>\$ (5,939)</u>	<u>\$ (27,155)</u>	<u>\$ (18,642)</u>	<u>\$ (49,459)</u>
Loss per share:				
Basic and diluted	<u>\$ (0.24)</u>	<u>\$ (1.53)</u>	<u>\$ (0.81)</u>	<u>\$ (4.58)</u>
Weighted average shares:				
Basic and diluted	<u>24,721</u>	<u>17,752</u>	<u>22,972</u>	<u>10,798</u>

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