

August 5, 2015

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

Opening of clinical sites in six countries builds momentum in MIN-101 Phase IIb schizophrenia trial

First patient dosed in Phase IIa study with MIN-117 in major depressive disorder

First patient dosed in Phase Ib study with MIN-202 as adjunctive treatment for major depressive disorder; MIN-202 data in insomnia presented at SLEEP meeting

Company adds to Board and management

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

WALTHAM, Mass., Aug. 5, 2015 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat central nervous system (CNS) disorders, today reported key business updates and financial results for the second quarter ended June 30, 2015.

"Measurable progress has been made in the initiation of clinical sites and enrollment for our Phase IIb trial with MIN-101 in schizophrenia and in the dosing of our first patient in the Phase IIa trial with MIN-117 for major depressive disorder," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "In addition, Janssen Pharmaceutica NV, our development partner, has dosed the first patient in a Phase Ib trial of MIN-202 (JNJ-42847922) as an adjunctive treatment for major depressive disorder and is planning to begin a Phase IIa trial in insomnia disorder under our co-development and license agreement.

"We believe that we are now well positioned to achieve our objectives through mid-2016, including data readouts from our most advanced programs, MIN-101 and MIN-117, which will represent significant steps to meeting unmet patient needs in CNS conditions." said Dr. Luthringer.

#### MIN-101:

• Approximately forty clinical sites have been initiated in six countries in the ongoing Phase IIb study with Minerva's lead compound, MIN-101, in schizophrenic patients with a history of negative symptoms. Sites have now been initiated in six countries, and patient enrollment is expected to continue through the end of 2015. The target patient recruitment goal is 234, with a third of patients dosed at 32 milligrams (mg) daily, a third at 64 mg daily and a 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-117:

• The first patient has been dosed in a Phase IIa clinical trial of MIN-117 in patients with major depressive disorder to compare the therapeutic impact of two doses of MIN-117, 0.5 mg and 2.5 mg daily, to paroxetine and to placebo. Eighty patients are expected to be enrolled in this trial, with 20 patients in each of the four groups. 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-202 (JNJ-42847922):

• Pre-clinical and early clinical data with MIN-202 were presented by Janssen at the 29<sup>th</sup> Annual Meeting of the Associated Professional Sleep Societies (SLEEP 2015). Janssen has dosed the first patient in a European Phase Ib study in adjunctive treatment of major depressive disorder and has opened an Investigational New Drug Application (IND) for this indication in the U.S. In addition, Minerva expects that Janssen will initiate a Phase IIa study with MIN-202 in insomnia disorder within the next few months. Data readouts for both trials are expected in the first half of 2016.

# MIN-301:

• Early in 2015, results were announced from a non-human primate study showing that treatment with an analog of MIN-301 resulted in

improvements in a range of symptoms associated with a Parkinson's disease model in primates. The next planned steps in this program are the filing of an IND in the U.S. or an Investigational Medicinal Product Dossier (IMPD) in Europe in 2016, and pending acceptance by regulatory authorities, the initiation of Phase I clinical testing thereafter.

### **Board and Management:**

- Fouzia Laghrissi-Thode, M.D. has been appointed to Minerva's board of directors. Dr. Laghrissi-Thode brings extensive experience in global pharmaceutical development to Minerva and has held positions of leadership at AstraZeneca, Roche, Novartis and Sandoz in a broad range of therapeutic areas. She is currently vice president of the cardiovascular and metabolism therapy area at AstraZeneca. Dr. Laghrissi-Thode holds an M.D. from the University Of Tours School Of Medicine in France, is board certified in psychiatry and is adjunct professor of psychiatry at the University of Pittsburgh.
- William Boni has been named vice president of investor relations and corporate communications. Mr. Boni joins Minerva from
  ArQule, Inc. He has more than 20 years of experience in the biopharmaceutical industry, including corporate positions with
  Interneuron / Indevus Pharmaceuticals and Curis, Inc. His agency experience includes Hill & Knowlton and Feinstein Partners. Mr.
  Boni is a graduate of Tufts University and holds a master's degree from Columbia University.

#### **Second Quarter 2015 Financial Results**

- Cash Position: Cash, cash equivalents and marketable securities (current and non-current) as of June 30, 2015 were approximately \$44.8 million, compared to \$18.5 million as of December 31, 2014. 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 \$4.5 million in the second quarter of 2015, compared to \$14.6 million in the second quarter of 2014. For the six months ended June 30, 2015, R&D expenses were \$8.4 million, compared to \$15.1 million for the six months ended June 30, 2014. The decreases in R&D expenses for the three and six months ended June 30, 2015 were primarily due to decreases in non-cash stock-based compensation expense of \$12.8 million in both periods. Excluding non-cash stock-based compensation expenses for the Company's drug development programs for the three and six months ended June 30, 2015 totaled \$4.3 million and \$8.2 million, respectively, versus \$1.6 million and \$2.1 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 six months ended June 30, 2015 of \$2.7 million and \$6.1 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 Phase I clinical trials.
- **G&A Expenses:** General and administrative (G&A) expenses were \$1.8 million in the second quarter of 2015, compared to \$3.1 million in the second quarter of 2014. For the six months ended June 30, 2015, G&A expenses were \$3.8 million, compared to \$5.1 million for the same period in 2014. The decreases in G&A expenses for the three and six months ended June 30, 2015 were primarily due to a decrease in non-cash stock-based compensation expense of \$1.1 million and \$1.3 million, respectively.
- Net Loss: Net loss was \$6.6 million for the second quarter of 2015, or a loss per share of \$0.27 (basic and diluted), as compared to a net loss of \$19.4 million, or a loss per share of \$2.55 (basic and diluted) for the second quarter of 2014. Net loss was \$12.7 million for the first six months of 2015, or a loss per share of \$0.58 (basic and diluted), as compared to a net loss of \$22.3 million, or a loss per share of \$3.07 (basic and diluted) for the first six 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 76101573.

The live webcast can be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at <a href="ir.minervaneurosciences.com">ir.minervaneurosciences.com</a>. 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 development for the treatment of schizophrenia; MIN-202 (JNJ-42847922), in development for the treatment of insomnia; MIN-117, in development for the treatment of major depressive disorder; and MIN-301, in 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

#### 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 June 30, 2015, filed with the Securities and Exchange Commission on August 5, 2015. 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)

June 30, December 31,

2015 2014

(in thousands)

#### **ASSETS**

Current Assets	:
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Cash and cash equivalents	\$ 21,735	\$ 18,546
Marketable securities - current portion	13,651	
Restricted cash	80	35
Prepaid expenses	309	757
Total current assets	35,775	19,338
Marketable securities - noncurrent	9,444	
Equipment, net	35	44
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	\$ 94,323	\$ 68,451

#### LIABILITIES AND STOCKHOLDERS' DEFICIT

## **Current Liabilities:**

Notes payable - current portion	\$ 1,087	\$
Accounts payable	564	642
Accrued expenses and other current liabilities	1,083	1,645

Accrued collaborative expenses	1,078	1,222
Total current liabilities	3,812	3,509
Long-Term Liabilities:		
Notes payable - noncurrent	8,697	
Deferred taxes	13,434	13,434
Other non-current liabilities	3	8
Total liabilities	25,946	16,951
Stockholders' Deficit:		
Common stock	2	2
Additional paid-in capital	155,810	126,229
Accumulated deficit	(87,435)	(74,731)
Total stockholders' deficit	68,377	51,500
Total Liabilities and Stockholders' Deficit	\$ 94,323	\$ 68,451

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

Three months ended June 30, Six months ended June 30, (in thousands, except per (in thousands, except per

share amounts)		share amounts)	
015	2014	2015	2014
\$	\$	\$	\$
4,485	14,555	8,446	15,140
1,847	3,095	3,765	5,133
6,332	17,650	12,211	20,273
(29)	10	(13)	4
(249)	(1,726)	(479)	(2,035)
6 (6,610)	\$ (19,366)	\$ (12,703)	\$ (22,304)
\$ (0.27)	\$ (2.55)	\$ (0.58)	\$ (3.07)
24,721	7,605	22,084	7,256
	\$ 4,485 1,847 6,332 (29) (249) 6 (6,610) \$ (0.27)	\$ \$  4,485	\$ \$ \$ \$ \$ \$ \$ 4,485

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