



November 6, 2014

Minerva Neurosciences Reports Third Quarter 2014 Financial Results

- *Advanced Lead Compound MIN-101 in Once-daily Formulation with Topline Results Expected in 4Q14; Phase 2b Study Expected to be Submitted in 4Q14 and Enrollment Expected to Begin in 1H15 -*
- *Phase 1 Bioavailability Study for MIN-202 in Insomnia in U.S. Ongoing after FDA Acceptance of IND Application; Topline Results Expected in 4Q14 -*
- *Management to Host Conference Call Today at 4:30 p.m. ET -*

WALTHAM, Mass., Nov. 6, 2014 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq:NERV), a leader in the development of innovative therapies to treat neuropsychiatric diseases and disorders, today reported business highlights and financial results for the third quarter ended September 30, 2014.

"During the past quarter, we continued to make important progress in our clinical development programs for schizophrenia and insomnia and look forward to announcing multiple milestones across both programs before the end of the year," said Rogerio Vivaldi, M.D., Chief Executive Officer of Minerva Neurosciences. "Our once-daily dose formulation study of MIN-101 is on track and we will look to establish the optimal once-daily dose formulation for our Phase 2b trials in schizophrenia, slated to begin in the first half of next year. In addition, in July the U.S. Food and Drug Administration accepted the Investigational New Drug application for MIN-202, which we plan to develop for insomnia, and we look forward to continuing to work with Janssen on the ongoing Phase 1 studies for this potential important new therapy."

Q3 Business Highlights

- **Advanced MIN-101, an Innovative Antagonist on 5-HT_{2A} and Sigma₂ Receptors, in Once-Daily Formulation for the Treatment of Schizophrenia:** Minerva Neurosciences initiated a new once-daily dose formulation study of MIN-101 consisting of two parts. Part 1 is a single dose administration to evaluate safety, tolerability and the pharmacokinetic profile of the compound. Part 2 is a multi-dose administration over seven days to determine central nervous system (CNS) pharmacodynamics effects and plasma pharmacokinetic profile of the compound. Safety and tolerability will be also assessed.
- **Phase 1 Bioavailability Study for MIN-202 in Insomnia in U.S. Ongoing after FDA Acceptance of IND Application:** Janssen initiated a randomized, open-label, three-way crossover Phase 1 study of MIN-202 to evaluate the bioavailability, food effect, and safety and tolerability of a solid dosage formulation of MIN-202 in healthy male volunteers. Minerva Neurosciences is co-developing MIN-202 with Janssen for the treatment of primary as well as secondary insomnia in multiple Phase 1 studies.
- **Strengthened Management Team:** In August, Minerva Neurosciences announced the appointment of Mark S. Levine as Vice President and General Counsel. Mr. Levine's over 17 years of experience as a corporate and commercial attorney further strengthens the Company's leadership team.

Today, Minerva Neurosciences announced the promotion of Remy Luthringer, PhD, to President and Chief Scientific Officer. Dr. Luthringer was formerly Executive Vice President and Head of R&D and has worked for the Company since its inception. In his new role, Dr. Luthringer will report to Minerva Neurosciences CEO Rogerio Vivaldi, M.D. and will be responsible for the evaluation, design and implementation of strategies to advance the Company's pipeline and R&D efforts. Dr. Luthringer has been involved in the development of more than 150 active molecules advanced to clinical stage research in the treatment of a broad range of CNS diseases and disorders.

Upcoming Milestones:

MIN-101

- **Topline results from the once-daily formulation study of MIN-101:** Minerva Neurosciences expects to announce these results in the fourth quarter of 2014.
- **Submission of a MIN-101 Phase 2b study in Europe:** Minerva Neurosciences plans to submit a multi-center, randomized, double-blind, parallel group design study in Europe in the fourth quarter of 2014, with enrollment expected

to begin in the first half of 2015. This trial will explore the effect of two doses of MIN-101 given once daily versus placebo in approximately 234 schizophrenic patients with confirmed negative symptoms.

MIN-202

- **Minerva Neurosciences also expects to announce results from the following studies for MIN-202:**
 - A Phase 1 bioavailability study with a solid formulation in healthy volunteers with topline results in the fourth quarter of 2014.
 - A Phase 1b study in patients with Major Depressive Disorder (MDD) where sleep and stress hormone levels will be explored with topline results in the first quarter of 2015.
 - A Phase 1 multiple ascending dose study in healthy volunteers, designed to evaluate the safety and tolerability of the drug with topline results in the first quarter of 2015.

Third Quarter 2014 Financial Results

- **R&D Expenses:** Research and development expenses were \$24.7 million in the third quarter of 2014, compared to \$0.2 million in the same period in 2013. Included in research and development expense for the third quarter of 2014 was \$22.0 million associated with the license fee payment made to Janssen pursuant to Minerva Neurosciences' co-development agreement for MIN-202 and non-cash stock-based compensation expense of \$0.1 million. Excluding non-cash stock based compensation expense and the \$22.0 million license fee, research and development expenses for the third quarter were \$2.6 million, versus \$0.2 million in the prior year period. This increase was primarily due to \$1.0 million related to a once-daily dose formulation study initiated in 2014 for MIN-101 and \$1.4 million in development costs for MIN-202 under the co-development agreement with Janssen.
- **G&A Expenses:** General and administrative expenses were \$2.4 million in the third quarter of 2014, compared to \$0.3 million in the same period in 2013. Excluding non-cash stock-based compensation expense of \$0.8 million, general and administrative expenses were \$1.6 million for the third quarter of 2014, versus \$0.3 million in the same period in 2013. The increase was primarily due to \$1.0 million related to staffing, office leases and information systems to support operations and \$0.3 million related to intellectual property matters and the Company's operations as a public reporting company.
- **Net Loss:** Net loss was \$27.2 million for the third quarter of 2014, or a loss per share of \$1.53 (basic and diluted), as compared to net loss of \$0.5 million, or a loss per share of \$0.12 (basic and diluted) for the same period in 2013.
- **Cash Position:** Cash and cash equivalents as of September 30, 2014 were \$23.6 million, compared to \$1.8 million as of December 31, 2013. In July 2014, the sale of approximately 5.6 million shares in an IPO (including the partial exercise of the underwriters' option to purchase additional shares) and approximately 0.7 million shares in a private placement resulted in net proceeds to the Company of approximately \$29.9 million, after deducting underwriter discounts, offering costs, loan repayments and a \$0.7 million license fee payment to ProteoSys. The Company also sold approximately 3.3 million shares in July 2014 in a second private placement with Janssen, resulting in gross proceeds of \$19.7 million. In conjunction with this private placement the Company made a \$22.0 million license fee payment to Janssen. Minerva Neurosciences expects that the proceeds from the IPO and private placements will be sufficient to fund its operating requirements through the end of 2015.

Conference Call Information

Minerva Neurosciences will host a conference call and live audio webcast today at 4:30 p.m. EST to discuss the quarter and recent business activities. To participate in the conference call, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 27580305. The live webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at www.minervaneurosciences.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event and will be archived for 30 days.

About Minerva

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat neuropsychiatric diseases. Minerva Neurosciences is developing a portfolio of first-in-class proprietary compounds, including lead compound MIN-101, which is in Phase 2 trials for schizophrenia, and additional candidates targeting MDD, insomnia and other CNS disorders. Minerva Neurosciences' common stock is listed on the NASDAQ Global Market where it trades 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, the timing of future clinical trials of and results of such clinical trials regarding MIN-101 and MIN-202, clinical and therapeutic potential of MIN-101 and MIN-202 and our ability to successfully develop and commercialize MIN-101 and MIN-202 and management's ability to successfully achieve its goals. These forward-looking statements are only predictions and may differ materially from actual results due to a variety of factors including, without limitation, whether MIN-101, MIN-202 or 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 MIN-101, MIN-202 and our other therapeutic products will be successfully marketed if approved; whether any of our other 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, 2014, filed with the Securities and Exchange Commission on November 6, 2014. Copies of reports filed with the SEC are posted on our website. 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.

Minerva Neurosciences, Inc.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(Unaudited)

	September 30, December 31,	
	2014	2013
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$23,640	\$1,818
Prepaid expenses	<u>584</u>	<u>1</u>
Total current assets	\$24,224	\$1,819
Equipment, net	35	3
In-process research and development	34,200	19,000
Goodwill	14,869	7,918
Deferred public offering costs	<u>----</u>	<u>434</u>
Total Assets	<u>\$73,328</u>	<u>\$29,174</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$942	\$523
Accrued expenses and other current liabilities	2,237	815
Convertible promissory notes	----	58
Derivative liability	<u>----</u>	<u>10</u>
Total current liabilities	<u>\$3,179</u>	<u>\$1,406</u>
Long-Term Liabilities:		
Deferred taxes	<u>13,434</u>	<u>7,589</u>
Total liabilities	<u>\$16,613</u>	<u>\$8,995</u>
Stockholders' Deficit:		
Common stock	2	1
Additional paid-in capital	124,002	38,008
Accumulated deficit	<u>(67,289)</u>	<u>(17,830)</u>
Total stockholders' deficit	<u>\$ 56,715</u>	<u>\$ 20,179</u>
Total Liabilities and Stockholders' Deficit	<u>\$73,328</u>	<u>\$29,174</u>

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)	
	2014	2013	2014	2013
Revenues	\$ ----	\$ ----	\$ ----	\$ ----
Operating expenses:				
Research and development	24,738	191	39,940	544
General and administrative	2,413	292	7,485	588
Total operating expenses	27,151	483	47,425	1,132
Foreign exchange (gains)/losses	(11)	2	(15)	3
Interest expense, net	15	3	2,049	-----
Net loss	\$ 27,155	\$ 488	\$ 49,459	\$ 1,135
Loss per share:				
Basic and diluted	\$1.53	\$0.12	\$4.58	\$0.29
Weighted average shares:				
Basic and diluted	17,752	4,091	10,798	3,859

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