



March 26, 2015

## Minerva Neurosciences Reports Fourth Quarter and Full Year 2014 Financial Results

*- MIN-101 Phase 2b trial for schizophrenia on track -*

*- Phase 2a trial planned for MIN-202 in primary insomnia in mid-2015; Phase 1b in MDD patients also expected to begin in mid-2015 -*

*- Company advancing CNS pipeline with MIN-117 and MIN-301 -*

*- Management to host conference call today at 4:30 p.m. ET -*

WALTHAM, Mass., March 26, 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) diseases and disorders, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2014.

"We are very pleased to report continued progress for each of our clinical development programs, and are looking forward to several upcoming milestones in 2015 and 2016," commented Dr. Remy Luthringer, president and chief executive officer of Minerva. "Following our recent private placement that resulted in net proceeds of approximately \$28.8 million, we now have in place additional financial resources to progress toward our goal of building a company with innovative therapeutics that we believe will address the unmet needs of patients across a range of CNS diseases."

### Fourth Quarter and Recent Business Highlights:

#### MIN-101:

- Minerva today announced that it received regulatory approval in Latvia, and ethical committee approvals in Latvia and Estonia, for the Phase 2b study for MIN-101, a serotonin 5-HT<sub>2A</sub> and sigma<sub>2</sub> receptor antagonist for the potential treatment of schizophrenia. The Company submitted an application to run a multi-center, randomized, double-blind, parallel group design study to local authorities in Europe in the fourth quarter of 2014, and enrollment is expected to occur in the last three quarters of 2015. This trial is exploring the effect of two doses of MIN-101 given once daily versus placebo in 234 schizophrenic patients with a history of negative symptoms.
- In December 2014, Minerva also announced the completion of development and final selection of a once-daily dose formulation of MIN-101. The new formulation will be used in the Company's planned Phase 2b clinical trial in schizophrenia and was assessed in a single-center, open-label trial to evaluate the safety, tolerability and pharmacokinetic profiles of several formulations of MIN-101 after administration of single doses of several dosages.

#### MIN-202:

- In March 2015, Minerva announced that two additional studies for MIN-202 are expected to be initiated in 2015. MIN-202 is a selective orexin-2 antagonist that the Company is developing as part of a collaboration with Janssen Research & Development, LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the treatment of primary and comorbid insomnia. The first is a Phase 2a study in primary insomnia which is expected to be initiated in mid-2015, and the second is a Phase 1b study in patients with major depressive disorder (MDD) with comorbid insomnia which is expected to be initiated in mid-2015.
- In January 2015, Minerva reported preliminary results from a Phase 1, placebo-controlled, clinical study conducted by Janssen showing that treatment with MIN-202 resulted in improvements in sleep onset and sleep duration in patients with comorbid insomnia related to MDD.
- Janssen also conducted two additional studies in 2014. The first, a randomized, open-label, three-way crossover Phase 1 study evaluated the bioavailability, food effect, and safety and tolerability of a solid dosage formulation as compared to the liquid formulation used in previous trials in healthy male volunteers, and the second was a double-blind, placebo-controlled, multiple-ascending dose study of several doses of MIN-202 in healthy volunteers.

#### MIN-117:

- Minerva also today announced that it received ethical committee approval in Latvia for a Phase 2a study for MDD in 60 patients, which is expected to begin enrolling in the second quarter of 2015. This will be a randomized, double-blind,

parallel-group, placebo and active-controlled study to evaluate the efficacy and safety of 0.5 mg of MIN-117 in adult subjects with MDD. The primary objective is to evaluate the efficacy of this dose compared to placebo in reducing the symptoms of a major depressive episode as measured by the change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score over 6 weeks of treatment. Safety and tolerability will also be explored in comparison to the active control paroxetine given at a therapeutic dose of 20 mg/day.

#### **MIN-301:**

- Minerva today announced that in 2016 it expects to file an Investigational New Drug (IND) or Investigational Medicinal Product Dossier (IMPD) for MIN-301, the Company's investigational neuregulin-1 beta1 compound for the treatment of Parkinson's disease. Following the acceptance of the IND or IMPD, as applicable, Minerva expects to initiate a Phase 1 clinical study.
- In January 2015, Minerva announced that results from a Primomed (use of PRIMate MOdels to support translational MEDicine) non-human primate study showed that treatment with an analog of MIN-301 resulted in improvements in a range of symptoms associated with Parkinson's disease. The analog used in the Primomed study differs from MIN-301 by a single amino acid.

#### **Corporate Highlights:**

- In November 2014, Minerva announced the appointment of Remy Luthringer, Ph.D., president and chief scientific officer, to the additional post of chief executive officer of the Company. Dr. Luthringer also joined the Board of Directors of Minerva.

#### **Fourth Quarter and Full Year Ended December 31, 2014 Financial Results:**

- **R&D Expenses:** Research and development expenses were \$3.0 million in the fourth quarter of 2014, compared to \$0.2 million in the same period in 2013. Research and development expenses were \$42.9 million for the full year ended December 31, 2014, compared to \$0.7 million in the same period in 2013. These increases were primarily due to increased costs related to the Company's four drug development programs, including a \$22.0 million license fee paid to Janssen under the co-development agreement for MIN-202, and increased costs for salaries and stock compensation expense related to additional staff hired during 2014.
- **G&A Expenses:** General and administrative expenses were \$4.5 million in the fourth quarter of 2014, compared to \$1.9 million in the same period in 2013. General and administrative expenses were \$12.0 million for the full year ended December 31, 2014, compared to \$2.5 million in the same period in 2013. These increases were primarily due to increased costs related to operations as a public company and increased costs for salaries and stock compensation expense related to additional staff hired during 2014.
- **Net Loss:** Net loss was \$7.4 million for the fourth quarter of 2014, or a loss per share of \$0.40 (basic and diluted), as compared to net loss of \$2.1 million, or a loss per share of \$0.41 (basic and diluted) for the same period in 2013. Net loss was \$56.9 million for the full year ended December 31, 2014, or a loss per share of \$4.47 (basic and diluted), as compared to net loss of \$3.3 million, or a loss per share of \$0.78 (basic and diluted) for the same period in 2013.
- **Cash Position:** Cash and cash equivalents as of December 31, 2014 were \$18.6 million, compared to \$1.8 million as of December 31, 2013. In January 2015 Minerva entered into a term loan with Oxford Financing LLC and Silicon Valley Bank for up to \$15.0 million. Under this agreement the Company drew down \$10.0 million in January 2015. In March 2015, Minerva issued approximately 6.3 million shares of common stock and warrants to purchase an additional approximately 6.3 million shares of common stock in a private placement resulting in net proceeds of approximately \$28.8 million, net of placement agent fees. Minerva expects that its current cash will fund the Company's operations through 2016.

#### **Conference Call Information:**

Minerva Neurosciences will host a conference call and live audio webcast today at 4:30 p.m. ET 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 9756969. The live webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at [www.minervaneurosciences.com](http://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 Neurosciences:**

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat CNS diseases. Minerva is developing proprietary compounds, including its lead program MIN-101 in development for the treatment of schizophrenia, MIN-202 in development for primary and comorbid 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 where it trades 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 benefits of and our ability to leverage the proceeds of our financings; 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; 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 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 Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 26, 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 DATA****(Unaudited)**

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 18,546	\$ 1,818
Restricted cash	35	--
Prepaid expenses	<u>757</u>	<u>1</u>
Total current assets	<u>\$ 19,338</u>	<u>\$ 1,819</u>
Equipment, net	44	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><u>\$ 68,451</u></u>	<u><u>\$ 29,174</u></u>

**LIABILITIES AND STOCKHOLDERS' DEFICIT**

Current Liabilities:		
Accounts payable	\$ 642	\$ 523
Accrued expenses and other current liabilities	1,645	815
Accrued collaborative expenses	1,222	--
Convertible promissory notes	--	58
Derivative liability	<u>--</u>	<u>10</u>
Total current liabilities	<u>\$ 3,509</u>	<u>\$ 1,406</u>
Long-Term Liabilities:		
Deferred taxes	13,434	7,589
Other non-current liabilities	<u>8</u>	<u>--</u>
Total liabilities	<u><u>\$ 16,951</u></u>	<u><u>\$ 8,995</u></u>
Stockholders' Deficit:		
Common stock	2	1

Additional paid-in capital	126,229	38,008
Accumulated deficit	<u>(74,731)</u>	<u>(17,830)</u>
Total stockholders' deficit	<u>\$ 51,500</u>	<u>\$ 20,179</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 68,451</u>	<u>\$ 29,174</u>

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Year Ended December 31,	
	(in thousands, except per share amounts)	
	<u>2014</u>	<u>2013</u>
Revenues	\$ --	\$ --
Operating expenses:		
Research and development	42,909	708
General and administrative	<u>11,962</u>	<u>2,467</u>
Total operating expenses	<u>54,871</u>	<u>3,175</u>
Foreign exchange (gains)/losses	19	(29)
Interest expense, net	<u>(2,050)</u>	<u>(58)</u>
Net loss	<u>\$ (56,902)</u>	<u>\$ (3,262)</u>
Loss per share:		
Basic and diluted	\$ (4.47)	\$ (0.78)
Weighted average shares:		
Basic and diluted	12,724	4,186

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Source: Minerva Neurosciences, Inc

