



May 7, 2015

## **Minerva Neurosciences Reports First Quarter 2015 Financial Results and Other Key Business Updates**

*MIN-101 Phase 2b trial for schizophrenia on track with enrollment underway; new regulatory approvals to conduct trials in Europe*

*MIN-117 Phase 2a study in Major Depressive Disorder (MDD) on track and expected to begin enrollment in second quarter; additional study arm planned*

*Management to host conference call today at 8:30 a.m. ET*

WALTHAM, Mass., May 7, 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 key business updates and financial results for the first quarter ended March 31, 2015.

"We significantly strengthened our balance sheet by successfully completing equity capital and debt financing in the first quarter of 2015," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "We also made important progress advancing our clinical development programs and achieving several clinical and regulatory milestones for our pipeline, including regulatory approval to begin our Phase 2b study of our lead product candidate MIN-101. We remain on track with our clinical programs as we approach several upcoming milestones in 2015 and key data readouts in the first half of 2016, which I believe will bring us closer to our goal of building a CNS company with innovative therapeutics to help patients with significant unmet needs."

### **First Quarter 2015 Key Business Updates:**

#### **MIN-101:**

- Minerva today announced that to date it has received regulatory approvals in Latvia, Estonia, Romania and Russia and ethical committee approvals in Latvia, Estonia and Romania 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. Enrollment in this trial has begun and is expected to continue through 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 stable schizophrenic patients with a history of negative symptoms. Topline results for the core part of the Phase 2b study are expected to be available in the second quarter of 2016.

#### **MIN-202:**

- In March 2015, Minerva announced that two additional studies are expected to be initiated in 2015 for MIN-202, a selective orexin-2 antagonist that Minerva is developing as part of a collaboration with Janssen Research & Development, LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. 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 MDD with comorbid insomnia which is expected to be initiated in mid-2015.

#### **MIN-117:**

- Minerva today announced that it plans to file an amendment to the protocol previously approved by Latvian regulatory authorities for the double blinded placebo controlled Phase 2a study in patients with MDD. The amendment will request an additional patient arm that would evaluate a 2.5mg dose of MIN-117. If the amended protocol is approved, the study is expected to include a total of 80 patients, of which 20 would receive a 0.5mg dose of MIN-117, 20 would receive a 2.5mg dose of MIN-117, 20 would receive a 20mg dose of paroxetine and 20 would receive a placebo. The additional arm would allow us to explore the relative improvement in symptoms between the patients receiving 0.5mg and 2.5mg doses of MIN-117. Minerva plans to begin enrollment for the Phase 2a study in the second quarter of 2015 and expects topline results to be available in the first half of 2016.

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

- In January 2015, Minerva announced that treatment with an analog of MIN-301, the Company's investigational neuregulin-

1 beta1 compound for the treatment of Parkinson's disease, resulted in improvements in a range of symptoms associated with Parkinson's disease in primates. The analog used in the study differs from MIN-301 by a single amino acid.

- In March 2015, Minerva announced that it expects to file an Investigational New Drug (IND) or Investigational Medicinal Product Dossier (IMPD) for MIN-301 in 2016. Following the acceptance of the IND or IMPD, as applicable, Minerva expects to initiate a Phase 1 clinical study.

#### **Financings:**

- In January 2015, Minerva announced that it had entered into a term loan with Oxford Financing LLC and Silicon Valley Bank for up to \$15.0 million and that it drew down \$10.0 million.
- In March 2015, Minerva announced that it 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 to the Company of approximately \$28.5 million, net of transaction costs.

#### **First Quarter 2015 Financial Results:**

- **Cash Position:** Cash and cash equivalents as of March 31, 2015 were \$52.2 million, compared to \$18.5 million as of December 31, 2014. Minerva expects that its current cash will fund its operations through 2016.
- **R&D Expenses:** Research and development expenses were \$4.0 million in the first quarter of 2015, compared to \$0.6 million in the same period in 2014. The increase was primarily due to program costs of \$1.6 million related to MIN-101, \$1.5 million in program costs related to MIN-202 and \$0.3 million of employee compensation.
- **G&A Expenses:** General and administrative expenses were \$1.9 million in the first quarter of 2015, compared to \$2.0 million in the same period in 2014. The decrease was primarily due to lower consulting fees, offset by higher employee compensation.
- **Net Loss:** Net loss was \$6.1 million for the first quarter of 2015, or a loss per share of \$0.31 (basic and diluted), as compared to net loss of \$2.9 million, or a loss per share of \$0.43 (basic and diluted) for the same period in 2014.

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

Minerva Neurosciences will host a conference call and live audio webcast today at 8:30 a.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 29475035. 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 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 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the Securities and Exchange Commission on May 7, 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)

	March 31, December 31,	
	2015	2014
	(in thousands)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 52,201	\$ 18,546
Restricted cash	40	35
Prepaid expenses	<u>503</u>	<u>757</u>
Total current assets	<u>\$ 52,744</u>	<u>\$ 19,338</u>
Equipment, net	34	44
In-process research and development	34,200	34,200
Goodwill	<u>14,869</u>	<u>14,869</u>
Total Assets	<u>\$ 101,847</u>	<u>\$ 68,451</u>

## LIABILITIES AND STOCKHOLDERS' DEFICIT

Current Liabilities:		
Notes payable - current portion	\$ 158	\$ --
Accounts payable	1,035	642
Accrued expenses and other current liabilities	1,771	1,645
Accrued collaborative expenses	<u>1,461</u>	<u>1,222</u>
Total current liabilities	<u>\$ 4,425</u>	<u>\$ 3,509</u>
Long-Term Liabilities:		
Notes payable - noncurrent	9,547	--
Deferred taxes	13,434	13,434
Other non-current liabilities	<u>5</u>	<u>8</u>
Total liabilities	<u>\$ 27,411</u>	<u>\$ 16,951</u>
Stockholders' Deficit:		
Common stock	2	2
Additional paid-in capital	155,258	126,229
Accumulated deficit	<u>(80,824)</u>	<u>(74,731)</u>
Total stockholders' deficit	<u>\$ 74,436</u>	<u>\$ 51,500</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 101,847</u>	<u>\$ 68,451</u>

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,	
	(in thousands, except per share amounts)	
	2015	2014
Revenues	\$ --	\$ --
Operating expenses:		
Research and development	3,961	586
General and administrative	<u>1,917</u>	<u>2,037</u>
Total operating expenses	<u>5,878</u>	<u>2,623</u>

Foreign exchange (gains)/losses	16	(6)
Interest expense, net	<u>(231)</u>	<u>(309)</u>
Net loss	<u>\$ (6,093)</u>	<u>\$ (2,938)</u>
Loss per share:		
Basic and diluted	\$ (0.31)	\$ (0.43)
Weighted average shares:		
Basic and diluted	19,417	6,903

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