



March 13, 2017

## **Minerva Neurosciences Reports Fiscal 2016 Fourth Quarter and Year End Financial Results and Business Updates**

**Multiple positive data readouts during 2016 provide foundation for initiation of advanced clinical trials with three product candidates in 2017**

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

WALTHAM, Mass., March 13, 2017 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat unmet medical needs of central nervous system (CNS) disorders, today reported key business updates and financial results for the fourth quarter and fiscal year ended December 31, 2016.

"Multiple data readouts during 2016 marked significant progress along the clinical development pathways for MIN-101 in schizophrenia, MIN-202 in insomnia disorder and major depressive disorder (MDD) and MIN-117 in MDD," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "These accomplishments set the stage for the expected initiation of advanced-stage and pivotal clinical trials in 2017. Our goal with each of these product candidates is to address unmet medical needs and thereby to expand the therapeutic options for patients suffering from these diseases."

### **MIN-101:**

- | During 2016, the Company announced positive results from both the randomized, double blind, placebo controlled core phase and the open label extension phase of its Phase IIb trial with MIN-101 for the treatment of schizophrenia. Statistically significant, specific improvements were observed in negative symptoms, the primary endpoint of the trial, as well as in multiple secondary endpoints, resulting from treatment with MIN-101 as monotherapy. Results from this trial were presented at the 2016 Annual Meeting of the American College of Neuropsychopharmacology (ACNP).
- | Following recent interactions with the U.S. Food and Drug Administration (FDA), an "end of Phase II" meeting has been scheduled with the FDA to take place early in the second quarter of 2017 to review the clinical and pre-clinical data with MIN-101 and to discuss the design of pivotal Phase III trials with this compound. A scientific advisory meeting will be scheduled thereafter with the European Medicines Agency (EMA). The Company expects to initiate Phase III testing of MIN-101 in schizophrenic patients with negative symptoms in the second half of 2017.

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

- | Data from a randomized, two way, cross-over placebo controlled, double blind Phase IIa clinical trial of MIN-202 in insomnia disorder were announced in the first quarter of 2016. Patients treated with MIN-202 were observed to experience statistically significant improvements in key sleep parameters compared to patients treated with placebo, including sleep efficiency as measured by objective polysomnography, the primary endpoint. Additional significant positive efficacy signals were observed for key secondary parameters.
- | Top line results from a randomized, double blind, parallel group Phase Ib clinical trial in MDD were announced in the first quarter of 2016. In this trial, consistently greater improvements in depressive symptomatology were observed in patients who received MIN-202 compared to those who received placebo or diphenhydramine, a positive control. Core symptoms of depression were also observed to significantly improve in patients treated with MIN-202, independent from its effect on sleep.
- | A number of supportive activities and clinical pharmacology studies are being conducted in anticipation of the next phase of clinical development with this compound in insomnia and MDD.

### **MIN-117:**

- | In a randomized, double blind, placebo and active controlled Phase IIa clinical trial in MDD, dose-dependent benefit of MIN-117 over placebo was observed. The trial was designed for signal detection and effect size estimation and not powered to

demonstrate statistical significance. Improvement in depressive symptomatology was observed after two weeks of treatment with MIN-117, and data showed that 24 percent of patients treated with the higher tested dose achieved remission as prospectively defined.

- | The FDA accepted the Investigational New Drug application (IND) for MIN-117 as announced in September, 2016. Acceptance of the IND allows the Company to begin clinical trials with this compound in the U.S. Planning is underway for these trials, which are expected to begin in late 2017.

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

- | The Company is pursuing the pre-clinical development of MIN-301 for the treatment of Parkinson's disease. MIN-301 is a peptide that targets the extra-cellular domain of neuregulin-1 beta-1 activating the ErbB4 receptor. The next planned steps in this program include the filing of an IND 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.

#### **Fourth Quarter and Year Ended 2016 Financial Results**

- | **Net Loss:** Net loss was \$9.4 million for the fourth quarter of 2016, or a loss per share of \$0.27 (basic and diluted), compared to a net loss of \$8.4 million for the fourth quarter of 2015, or a loss per share of \$0.34 (basic and diluted). Net loss was \$31.0 million for the year ended December 31, 2016, or a loss per share of \$0.99 (basic and diluted), compared to a net loss of \$27.1 million, or a loss per share of \$1.16 (basic and diluted), for the year ended December 31, 2015.
- | **R&D Expenses:** Research and development (R&D) expenses were \$6.5 million in the fourth quarter of 2016, compared to \$6.3 million in the fourth quarter of 2015. R&D expenses were \$20.4 million for the year ended December 31, 2016, compared to \$18.5 million for the year ended December 31, 2015. This increase in research and development expenses primarily reflects higher development expenses under the MIN-202 program for Phase II clinical trial preparation, and an increase in non-cash stock-based compensation expenses. This increase was partially offset by decreased expenses due to the completion of our Phase IIb clinical trial of MIN-101.
- | **G&A Expenses:** General and administrative (G&A) expenses were \$2.7 million in the fourth quarter of 2016, compared to \$1.9 million in the fourth quarter of 2015. G&A expenses were \$9.8 million for the year ended December 31, 2016, compared to \$7.6 million for the year ended December 31, 2015. The increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation expenses, personnel costs and professional fees during the year ended December 31, 2016.
- | **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2016 were approximately \$83.0 million, compared to \$32.2 million as of December 31, 2015. During 2016, the Company received approximately \$23.4 million in proceeds from the exercise of warrants granted in connection with a private placement in March 2015, approximately \$1 million from a common stock purchase by a director of the Company, and net proceeds of approximately \$53.7 million from a public offering of common stock. Minerva presently expects that its existing cash and cash equivalents will be sufficient to meet its anticipated capital requirements for at least the next 12 months from today. The assumptions upon which this estimate is based are under constant review and subject to change. The actual amount and timing of the Company's research and development expenditures may vary depending upon a number of factors, including but not limited to those related to the design, timing and duration of future clinical trials.

#### **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 63111094.

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 product candidates to treat CNS diseases. Minerva's proprietary compounds include: MIN-

101, in clinical development for schizophrenia; MIN-117, in clinical development for major depressive disorder (MDD); MIN-202 (JNJ-42847922), in clinical development for insomnia and MDD; and MIN-301, in pre-clinical development for 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 and pre-clinical milestones with MIN-101, MIN-202, MIN-117 and MIN-301; the timing and scope of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these compounds; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; 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 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-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 13, 2017. 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)**

**December 31,      December 31,**  
**2016                      2015**  
**(in thousands)**

#### **ASSETS**

Current Assets:

Cash and cash equivalents	\$ 82,981	\$ 14,284
Marketable securities	-	17,921
Restricted cash	80	80
Prepaid expenses and other current assets	803	1,196
Total current assets	83,864	33,481
Equipment, net	10	26
In-process research and development	34,200	34,200
Goodwill	14,869	14,869
Total Assets	\$ 132,943	\$ 82,576

#### **LIABILITIES AND STOCKHOLDERS' EQUITY**

Current Liabilities:

Notes payable - current portion	\$ 4,854	\$ 1,435
Accounts payable	1,467	1,360
Accrued expenses and other current liabilities	816	2,525

Accrued collaborative expenses	2,548	-
Total current liabilities	9,685	5,320
Long-Term Liabilities:		
Notes payable - noncurrent	3,841	8,503
Deferred taxes	13,434	13,434
Total liabilities	26,960	27,257
Stockholders' Equity:		
Common stock	4	2
Additional paid-in capital	238,837	157,130
Accumulated deficit	(132,858)	(101,813)
Total stockholders' equity	105,983	55,319
Total Liabilities and Stockholders' Equity	\$ 132,943	\$ 82,576

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

Year Ended December 31,  
(in thousands, except per share amounts)

	2016	2015
Revenues	\$ -	\$ -
Operating expenses:		
Research and development	20,440	18,533
General and administrative	9,751	7,577
Total operating expenses	30,191	26,110
Foreign exchange losses	(23)	(16)
Investment income	198	97
Interest expense	(1,030)	(1,053)
Net loss	\$ (31,046)	\$ (27,082)
Loss per share:		
Basic and diluted	\$ (0.99)	\$ (1.16)
Weighted average shares:		
Basic and diluted	31,514	23,412

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VP, Investor Relations/

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