March 14, 2016

# Minerva Neurosciences Reports Fiscal 2015 Fourth Quarter and Year End Financial Results and Business Updates

**Clinical trial advancements during 2015 support multiple top line data readouts in first half of 2016**

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

WALTHAM, Mass., March 14, 2016 (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, 2015.

"Minerva is positioned to deliver a series of significant clinical milestones during the first half of 2016 with three first-in-class compounds to treat schizophrenia (MIN-101), primary insomnia (MIN-202), comorbid insomnia in patients suffering from major depressive disorder, or MDD, (MIN-202), and MDD (MIN-117)," said Dr. Remy Luthringer, president and chief executive officer of Minerva.

**MIN-101:**

- The Company has completed enrollment of 244 patients in its ongoing Phase IIb, double-blind, placebo controlled trial testing MIN-101, a first-in-class 5-HT2a and sigma2 antagonist for the treatment of schizophrenia. The primary objective of this trial is to evaluate the efficacy of MIN-101 given at once-a-day doses of 32 and 64 milligrams (mg) in the morning compared to placebo in improving the negative symptoms of schizophrenic patients over 12 weeks of treatment, as measured by the change from baseline in the Positive and Negative Syndrome Scale (PANSS). Secondary objectives include assessment of the effect of MIN-101 on the total PANSS score and sub-scores, cognition and sleep. Safety and tolerability of the drug will also be monitored. Patients who respond positively to treatment during the 12-week double-blind period of the trial have the opportunity to enter an extension period of six months, during which all patients will be on active treatment. Top line results for the core 12-week treatment evaluation period are expected in the second quarter of 2016.
- The U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for MIN-101. Acceptance of the IND for MIN-101 supports the initiation of clinical testing of this compound in the U.S.

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

- MIN-202, a selective orexin-2 receptor antagonist, has been evaluated in three clinical trials, including a Phase IIa trial in insomnia disorder conducted in the U.S. and Europe, a Phase Ib trial as an adjunctive treatment to marketed antidepressants in patients suffering from MDD with insomnia as a comorbid symptom conducted in Europe, and a Phase I trial in healthy Japanese men.
- The Phase IIa trial in patients suffering from insomnia disorder without psychiatric comorbidity was a randomized, placebo-controlled double-blind, two way cross-over study to evaluate treatment with MIN-202 (40 mg daily given in the evening for five consecutive days) versus placebo in 28 study participants. Patients treated with MIN-202 were observed to have statistically significant improvements, as compared to placebo, in all key sleep parameters assessing sleep induction and sleep maintenance. These parameters, measured by objective polysomnography, include sleep efficiency (SE), the primary endpoint of the trial, for which a positive and statistically significant efficacy signal was detected versus placebo ($p < 0.001$). Additional statistically significant positive efficacy signals were observed for key secondary parameters, including latency to persistent sleep (LPS), wake after sleep onset (WASO), and total sleep time (TST). MIN-202 did not affect deep sleep, an important sleep stage affecting physiological functions such as memory consolidation. Compared to placebo, MIN-202 was observed to significantly improve polysomnography parameters ($p < 0.001$) on Days 1 and 5. On Day 5, LPS and WASO were reduced by 23.2 and 11 minutes and TST and SE increased by 39 minutes and 8.12 percent, respectively. No serious adverse events were observed in this trial, and preliminary data indicate that MIN-202 was well tolerated by patients.
- The Phase Ib trial was a randomized, double-blind, parallel group, positive diphenhydramine and placebo-controlled study to evaluate treatment with MIN-202 in 48 subjects with a diagnosis of MDD and treated with marketed antidepressants. The treatment duration was one month. Safety and tolerability, as well as effects on mood, cognition and stress hormone levels,

were assessed. Consistently greater improvements in depressive symptomatology were observed in patients randomized to receive MIN-202 compared to those randomized to receive placebo (PLA) or diphenhydramine (DPH), as measured by clinician administered rating scales, including the Hamilton Depression Rating Scale ($HDRS_{17}$). Core symptoms of depression (as measured by the $HAM\text{-}D_6$) were observed to be significantly improved in the MIN-202 arm when compared with the PLA arm. MIN-202 was observed to be well tolerated by study participants over a one-month treatment duration, with no new emerging safety signals and no serious adverse events.

- The Phase I trial in 24 healthy Japanese adult male study participants was a single center, double blind, placebo-controlled randomized single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MIN-202. It was observed that single dose morning administration of MIN-202 was well tolerated at 5 mg, 20 mg and 40 mg. The observed plasma pharmacokinetic features were comparable to those observed in previous studies carried out in healthy non-Asian study participants. No clinically relevant safety concerns were observed based on the assessment of multiple safety endpoints. Somnolence was the most frequently reported adverse event at the two higher doses, an expected finding as this compound is being developed as a treatment for patients suffering from insomnia disorder and as adjunctive treatment for MDD.

**MIN-117:**

- The Company has completed enrollment of patients with MDD in its ongoing Phase IIa, double-blind, parallel group design, placebo- and active-controlled clinical trial in Europe of MIN-117, a compound that targets multiple receptors known to be involved in mood disorders. Eighty-four patients were enrolled across the four treatment arms of this study (0.5 and 2.5 mg daily of MIN-117, placebo, and 20 mg daily of paroxetine). The primary endpoint of the trial is the efficacy of MIN-117 versus placebo in reducing the symptoms of a major depressive episode as measured by the Montgomery-Asberg Depression Rating Scale over six weeks of treatment. Secondary endpoints include assessments of onset of mood improvement, cognition, sexual function and sleep. Top-line results are expected in the second quarter of 2016.

**MIN-301:**

- Following a non-human primate study showing that treatment with an analog of MIN-301 improved a range of symptoms associated with a Parkinson's disease model, the Company is pursuing the pre-clinical development of this compound, which is the extra-cellular domain of neuregulin-1 beta primarily activating Erb4. The next planned steps in this program are the filing of an IND in the United States, 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 2015 Financial Results

- **Net Loss:** Net loss was $8.4 million for the fourth quarter of 2015, or a loss per share of $0.34 (basic and diluted), compared to a net loss of $7.4 million for the fourth quarter of 2014, or a loss per share of $0.40 (basic and diluted). Net loss was $27.1 million for the year ended December 31, 2015, or a loss per share of $1.16 (basic and diluted), compared to a net loss of $56.9 million, or a loss per share of $4.47 (basic and diluted), for the year ended December 31, 2014.

- **R&D Expenses:** Research and development (R&D) expenses were $6.3 million in the fourth quarter of 2015, compared to $3.0 million in the fourth quarter of 2014. R&D expenses were $18.5 million for the year ended December 31, 2015, compared to $42.9 million for the year ended December 31, 2014. R&D expenses for the year ended December 31, 2014 included a $22.0 million license fee paid to Janssen pursuant to our co-development agreement for MIN-202. R&D expenses for the years ended December 31, 2015 and 2014 included non-cash stock-based compensation expenses of $0.6 million and $13.1 million, respectively. Excluding stock-based compensation and the $22.0 million license fee, total R&D expenses related to drug development programs for the years ended December 31, 2015 and 2014 were $17.9 million and $7.8 million, respectively, an increase of $10.1 million. This increase in R&D expenses primarily reflects increased expenses related to our Phase IIb clinical trial of MIN-101, our Phase IIa clinical trial of MIN-117 and the MIN-202 Phase IIa and Ib clinical trials.

- **G&A Expenses:** General and administrative (G&A) expenses were $1.9 million in the fourth quarter of 2015, compared to $4.5 million in the fourth quarter of 2014. G&A expenses were $7.6 million for the year ended December 31, 2015, compared to $12.0 million for the year ended December 31, 2014. G&A expenses for the years ended December 31, 2015 and 2014 included non-cash stock-based compensation expenses of $1.6 million and $4.9 million, respectively. Excluding stock-based compensation, G&A expenses for the years ended December 31, 2015 and 2014 were $6.0 million and $7.1 million, respectively.

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2015 were approximately $32.2 million, compared to $18.5 million as of December 31, 2014. In the first quarter of 2016, the Company received approximately $17.5 million in proceeds from the exercise by certain existing stockholders of warrants granted in connection with a private placement in March 2015. Warrants with respect to a total of 3,039,514 shares of common stock were exercised at an exercise price of $5.77 per share. As a result, Minerva expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operations into the second quarter of 2017.

**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 49677445.

The live webcast can be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at 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 products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, in Phase IIb development for schizophrenia; MIN-202 (JNJ-42847922), in Phase IIa and Phase Ib development for insomnia and adjunctive treatment of MDD, respectively; MIN-117, in Phase IIa development for 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.

***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 of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these 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 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, 2015, filed with the Securities and Exchange Commission on March 14, 2016. 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)**

| | December 31, 2015 | December 31, 2014 |
|---|---|---|

**(in thousands)**

| | | |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 14,284 | $ 18,546 |
| Marketable securities - current portion | 17,921 | - |
| Restricted cash | 80 | 35 |
| Prepaid expenses | 1,196 | 757 |
| Total current assets | 33,481 | 19,338 |
| Marketable securities - noncurrent | - | - |
| Equipment, net | 26 | 44 |
| In-process research and development | 34,200 | 34,200 |
| Goodwill | 14,869 | 14,869 |
| Total Assets | $ 82,576 | $ 68,451 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' DEFICIT** | | |
| Current Liabilities: | | |
| Notes payable - current portion | $ 1,435 | $ - |
| Accounts payable | 1,360 | 642 |
| Accrued expenses and other current liabilities | 2,525 | 1,645 |
| Accrued collaborative expenses | - | 1,222 |
| Total current liabilities | 5,320 | 3,509 |
| Long-Term Liabilities: | | |
| Notes payable - noncurrent | 8,503 | - |
| Deferred taxes | 13,434 | 13,434 |
| Other non-current liabilities | - | 8 |
| Total liabilities | 27,257 | 16,951 |
| Stockholders' Deficit: | | |
| Common stock | 2 | 2 |
| Additional paid-in capital | 157,130 | 126,229 |
| Accumulated deficit | (101,813) | (74,731) |
| Total stockholders' deficit | 55,319 | 51,500 |
| Total Liabilities and Stockholders' Deficit | $ 82,576 | $ 68,451 |

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(Unaudited)**

| | Year Ended December 31, (in thousands, except per share amounts) | |
|---|---|---|
| | **2015** | **2014** |
| Revenues | $ - | $ - |
| Operating expenses: | | |
| Research and development | 18,533 | 42,909 |
| General and administrative | 7,577 | 11,962 |
| Total operating expenses | 26,110 | 54,871 |
| Foreign exchange (losses)/gains | (16) | 19 |
| Investment income | 97 | - |
| Interest expense | (1,053) | (2,050) |
| Net loss | $ (27,082) | $ (56,902) |
| Loss per share: | | |
| Basic and diluted | $ (1.16) | $ (4.47) |
| Weighted average shares: | | |
| Basic and diluted | 23,412 | 12,724 |


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