# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 11, 2016**

# Minerva Neurosciences, Inc.
**(Exact name of registrant as specified in its charter)**

| Delaware | 001-36517 | 26-0784194 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| 1601 Trapelo Road<br>Suite 284<br>Waltham, MA | 02451 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**(Registrant's telephone number, including area code): (617) 600-7373**

**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01 Regulation FD Disclosure**

On January 11, 2016, Minerva Neurosciences, Inc. (the "Company") issued a press release announcing top line results from a Phase 2A clinical trial in primary insomnia disorder with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV.

A copy of the above referenced press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. This information, including the information contained in the press release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company's filings, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of the Company dated January 11, 2016 |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**MINERVA NEUROSCIENCES, INC.**

By: /s/ Mark S. Levine
Name: Mark S. Levine
Title: Senior Vice President, General Counsel and Secretary

Date: January 11, 2016

**INDEX OF EXHIBITS**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release of the Company dated January 11, 2016 |

**Exhibit 99.1**

**Contact:**

William B. Boni
VP, Investor Relations/
Corp. Communications
Minerva Neurosciences, Inc.
(617) 600-7376

**FOR IMMEDIATE RELEASE**

# MINERVA NEUROSCIENCES ANNOUNCES FAVORABLE TOP LINE RESULTS FROM MIN-202 PHASE 2A CLINICAL TRIAL IN INSOMNIA DISORDER

## Consistent improvements observed with selective orexin-2 receptor antagonist in multiple parameters of sleep induction and maintenance

Waltham, MA, January 11, 2016 – Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies for central nervous system (CNS) disorders, today announced favorable top line results from a Phase 2A clinical trial in insomnia disorder with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV.

"These findings were generated with our selective orexin-2 receptor antagonist, MIN-202, which is designed to physiologically regulate biological rhythm and control of the overactive wake drive," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "The data indicate that MIN-202 may accelerate sleep induction, restore sleep duration and preserve key phases of sleep, thus enabling restorative sleep."

Patients treated with MIN-202 in the Phase 2A trial were observed to have statistically significant improvements in key sleep parameters, compared to patients treated with placebo. These parameters include sleep efficiency as measured by objective polysomnography, the primary endpoint of the trial, for which a positive efficacy signal was detected for 40 milligrams MIN-202 versus placebo ($p<0.001$). Additional significant positive efficacy signals were observed for key secondary parameters, including latency to persistent sleep, wake after sleep onset, and total sleep time.

No serious adverse events were observed in this trial, and preliminary data indicate that MIN-202 was well tolerated by patients. The most common treatment-emergent adverse events associated with exposure to MIN-202 during the double-blind phase of the study were somnolence and abnormal dreams.

The trial was conducted at clinical sites in the U.S. and Europe. Complete results are planned for peer-reviewed presentation in the future.

The Phase 2A trial was a randomized, two way, cross-over, placebo-controlled double-blind study to evaluate the effect of MIN-202 on sleep and daytime functioning in 28 patients with insomnia disorder without psychiatric co-morbidity. Patients were given MIN-202 or placebo in a cross-over design for treatment periods of five days, separated by a washout period.

In addition to this trial, a Phase 1B trial with MIN-202 is ongoing in patients suffering from major depressive disorder (MDD). In this trial, MIN-202 is co-administered with an antidepressant compound. Enrollment in this trial has been completed, and top line data are expected in the first quarter of 2016.

Minerva entered into a co-development and license agreement with Janssen in February, 2014 covering MIN-202 and any other orexin-2 compounds. Under this agreement, Minerva has an exclusive license to these compounds in the European Union, Switzerland, Liechtenstein, Iceland and Norway. Janssen has exclusive rights to these compounds worldwide outside of these territories.

**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 2B development for schizophrenia; MIN-202 (JNJ-42847922), in Phase 2A and Phase 1B development for insomnia and adjunctive treatment of MDD, respectively; MIN-117, in Phase 2A 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 milestones regarding MIN-202; the timing of future clinical trials and results of clinical trials regarding MIN-202; the clinical and therapeutic potential of MIN-202; our ability to successfully develop and commercialize MIN-202; 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 final data from the Phase 2A MIN-202 trial will be consistent with the preliminary results, whether MIN-202 will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether MIN-202 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful for MIN-202; 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, 2015, filed with the Securities and Exchange Commission on November 5, 2015. 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.*

**Source: Minerva Neurosciences, Inc.**