# 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): December 29, 2015**

# 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**<br>**(Address of principal executive offices)** | **02451**<br>**(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 December 29, 2015, Minerva Neurosciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has accepted the Company's Investigational New Drug application for MIN-101 for the treatment of schizophrenia. The Company also announced that it has completed enrollment in its ongoing European Phase IIb clinical trial of MIN-101.

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 December 29, 2015 |

**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: December 29, 2015

**INDEX OF EXHIBITS**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of the Company dated December 29, 2015 |

**Exhibit 99.1**

**Contact**:

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

**FOR IMMEDIATE RELEASE**

# MINERVA NEUROSCIENCES ANNOUNCES UPDATE ON MIN-101 CLINICAL DEVELOPMENT PROGRAM

## Enrollment completed in European Phase IIb trial and Investigational New Drug (IND) application accepted by U.S. FDA

Waltham, MA, December 29, 2015 – Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for MIN-101, a first-in-class 5-HT2a and sigma2 antagonist in clinical development for the treatment of schizophrenia.

In addition, the Company announced the completion of the enrollment of a total of 244 patients in a randomized, placebo-controlled double-blind European Phase IIb clinical trial of MIN-101. The primary objective of this trial is to evaluate the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenic patients. Additional objectives include the assessment of cognitive symptoms and overall symptomatology of the disease following treatment with MIN-101. Topline results from the core 12-week treatment evaluation period are expected in the second quarter of 2016.

"Acceptance of the IND for MIN-101 is an important step toward the initiation of advanced-stage clinical testing of this compound in the U.S. following the results of our ongoing Phase IIb trial in Europe," said Remy Luthringer, president and chief executive officer of Minerva. "We will be continuing our dialogue with the FDA as part of our overall planning for late-stage clinical testing in the U.S."

**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 the adjunctive treatment of major depressive disorder (MDD), respectively; MIN-117, in 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 with MIN-101; the clinical and therapeutic potential of MIN-101; our ability to successfully develop and commercialize MIN-101; 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 MIN-101 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-101 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts with MIN-101 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 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.*