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

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**FORM 8-K**

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**CURRENT REPORT**

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

Date of Report (Date of earliest event reported): May 26, 2016

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**Minerva Neurosciences, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36517**  
(Commission  
File Number)

**26-0784194**  
(I.R.S. Employer  
Identification No.)

**1601 Trapelo Road**  
**Suite 284**  
**Waltham, MA**  
(Address of principal executive offices)

**02451**  
(Zip Code)

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

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

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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))
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**Item 8.01 Other Events**

On May 26, 2016, Minerva Neurosciences, Inc. (the "Company") issued a press release announcing top line results from a Phase IIb clinical trial in schizophrenia with MIN-101 and issued a press release announcing top line results from a Phase IIa clinical trial in major depressive disorder with MIN-117. Copies of the above referenced press releases are filed as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated May 26, 2016 for MIN-101 Results
99.2	Press Release of the Company dated May 26, 2016 for MIN-117 Results

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**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: May 26, 2016

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**INDEX OF EXHIBITS**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press Release of the Company dated May 26, 2016 for MIN-101 Results
99.2	Press Release of the Company dated May 26, 2016 for MIN-117 Results

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

**FOR IMMEDIATE RELEASE**

**MINERVA NEUROSCIENCES ANNOUNCES POSITIVE RESULTS FROM PHASE IIB TRIAL  
OF MIN-101 MONOTHERAPY IN SCHIZOPHRENIA**

**MIN-101 meets primary and secondary endpoints**

- **Statistically significant improvement in PANSS negative symptoms and total PANSS scores observed**
- **MIN-101 shown to be statistically superior on key secondary endpoints**
- **Effect of MIN-101 demonstrated to be specific for negative symptoms and not secondary to improvement in other symptoms**

Waltham, MA, May 26, 2016 – 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 positive top line results from a prospective Phase IIB, 12-week, randomized, double-blind, placebo-controlled parallel clinical trial evaluating the efficacy, safety and tolerability of MIN-101 in patients with negative symptoms of schizophrenia. These negative symptoms, for which no approved treatment is currently available, affect the majority of schizophrenic patients and can persist over their lifetimes.

The study successfully achieved its primary endpoint, demonstrating the statistically significant benefit of MIN-101 over placebo in improving negative symptoms as measured by the pentagonal structure model (PSM) of the Positive and Negative Syndrome Scale (PANSS). The effect was shown for both doses tested: 32 mg:  $p \leq 0.022$  with an effect size of 0.45, and 64 mg:  $p \leq 0.003$  with effect size of 0.58.

The study also demonstrated statistically significant benefit of MIN-101 over placebo on the PANSS three factors negative symptoms subscale for both doses tested: 32 mg:  $p \leq 0.006$ , with an effect size of 0.55, and 64 mg:  $p \leq 0.001$  with an effect size of 0.70. Furthermore, the statistically significant benefit of MIN-101 over placebo was demonstrated on the PANSS total score (not significant for the 32 mg dose;  $p \leq 0.003$  for the 64 mg dose), with effect sizes of 0.35 and 0.59, respectively.

The consistency and robustness of the effect was also supported by the demonstrated statistically significant benefit of MIN-101 over placebo in multiple secondary endpoints as measured by the following: the PANSS general psychopathology subscale, Brief Negative Symptoms Scale (BNSS) total score, Clinical Global Impression of Severity (CGI-S), Clinical Global Impression of Improvement (CGI-I), Personal and Social Performance (PSP) total score and Brief Assessment of Cognition in Schizophrenia (BACS). Positive symptoms were observed to remain stable, and the absence of extra-pyramidal symptoms throughout the three month trial is consistent with the hypothesis that MIN-101 has a direct and specific effect on negative symptoms rather than an indirect effect mediated by improvements of positive symptoms.

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MIN-101 was generally reported to be well tolerated, and the incidence and types of side effects did not differ significantly between the MIN-101 group and the placebo group. Based upon previous non-clinical and clinical experience, QTcF, a measurement of cardiac function, was closely monitored. Discontinuation criteria based on QTcF prolongation were incorporated in the protocol. Two patients out of 162 who received MIN-101 were discontinued based upon these criteria; both of these patients received the higher dose (64 mg). Unlike many currently marketed antipsychotic drugs, no metabolic adverse effects, no weight gain and no extra-pyramidal symptoms were observed.

“We believe the results from this trial constitute a key step forward in the development of a novel treatment for schizophrenia and specifically the negative symptoms of the disease, which represent a significant unmet medical need,” said Dr. Remy Luthringer, president and chief executive officer of Minerva. “Negative symptoms contribute substantially to poor quality of life and functional outcomes of schizophrenic patients.

“We also observed consistent improvements in multiple secondary endpoints,” said Dr. Luthringer. “This broad impact underscores the potential of MIN-101, a molecule that combines sigma2 antagonism and 5-HT2a antagonism, as a promising differentiated treatment for a debilitating disease affecting large numbers of underserved patients worldwide. Because negative symptoms are not only present in schizophrenia but also in brain degenerative disorders and other mental illnesses, we believe that MIN-101 may be a candidate for the potential treatment of other indications.”

**About this study** (<https://www.clinicaltrialsregister.eu>, EudraCT Number: 2014-004878-42)

This was a prospective trial designed to evaluate the efficacy of MIN-101 monotherapy on negative symptoms using the pentagonal structure model (PSM) of the Positive and Negative Syndrome Scale (PANSS) as the primary endpoint. A total of 244 patients were randomized in equal groups to receive daily doses of MIN-101 32 mg, MIN-101 64 mg or placebo at 32 clinical sites in Russia and five European countries. To participate in the trial, patients were required to have stable positive and negative symptoms for three months prior to entry, a PANSS negative sub-score greater than or equal to 20, and scores < 4 on the following PANSS items: excitement, hyperactivity, hostility, suspiciousness, uncooperativeness and poor impulse control. All three cohorts were balanced with respect to demographic and baseline disease characteristics.

Secondary and exploratory outcomes included PANSS total and subscale scores, the Brief Assessment of Cognition in Schizophrenia (BACS), Brief Negative Symptoms Scale (BNSS), Clinical Global Impression of Severity (CGI-S), Clinical Global Impression of Improvement (CGI-I), the Calgary Depression Scale for Schizophrenia (CDSS), the Personal and Social Performance (PSP), and the Pittsburgh Sleep Quality Index (PSQI).

Patients who completed the 12-week double-blind core phase of this study were provided the opportunity to enter into the ongoing 24-week, open-label extension phase, which will provide additional long term safety and efficacy data. During the extension phase, all patients are receiving either 32 mg or 64 mg of MIN-101. Patients who received placebo in the core study were randomized to one of these two doses. The extension phase is expected to be completed during the third quarter of 2016.

#### **About schizophrenia and the impact of negative symptoms**

Schizophrenia remains among the top ten disabling conditions worldwide for young adults and affects more than 21 million people worldwide. According to Datamonitor, an independent market research firm, in 2015 approximately 3.2 million people suffered from schizophrenia in the United States, Japan and the five major European Union markets of France, Germany, Italy, Spain and the United Kingdom.

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Although positive psychotic symptoms are characteristic of schizophrenia, negative symptoms constitute the main burden of illness, represent an important treatment target and are responsible for the poor vocational and social capabilities of these patients. These symptoms, which include a-motivation, avolition, lack of initiative, and restricted personal interaction, are associated with poor psychosocial functioning.

Most current pharmacological therapies ameliorate positive, psychotic symptoms in most but not all schizophrenic patients. However, there currently exists no effective treatment for negative symptoms.

#### **About MIN-101**

MIN-101 is a drug candidate with equipotent affinities for sigma 2 and 5-hydroxytryptamine-2A (5-HT<sub>2A</sub>) and lower affinity at  $\alpha$ 1-adrenergic receptors. In preclinical studies and in a phase IIa trial, MIN-101 showed significant efficacy against negative symptoms.

#### **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), which has completed Phase IIa and Phase Ib clinical trials in insomnia and the adjunctive treatment of major depressive disorder (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](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 with MIN-101; the clinical and therapeutic potential of MIN-101; our ability to successfully develop and commercialize MIN-101; 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 the results of our future clinical trials with MIN-101, if any, will be consistent with the results of past clinical trials; 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*

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*Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 3, 2016. 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.*



**Contact:**

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

**FOR IMMEDIATE RELEASE**

**MINERVA NEUROSCIENCES ANNOUNCES POSITIVE RESULTS IN PHASE IIA TRIAL OF  
MIN-117 IN MAJOR DEPRESSIVE DISORDER**

**MIN-117 meets primary and secondary endpoints**

- **Reduction in depressive symptoms demonstrated**
- **Good tolerability and safety profile observed**
- **Positive effect on sleep architecture shown**
- **Differentiated mechanism of action**

Waltham, MA, May 26, 2016 – 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 positive top line results from a Phase IIA clinical trial in major depressive disorder (MDD) with MIN-117, an antidepressant drug candidate with a differentiated mechanism of action targeting adrenergic alpha 1a, alpha 1b, 5-HT1A, 5-HT2A receptors, serotonin and the dopamine transporter.

Results demonstrated dose-dependent superiority of MIN-117 over placebo as measured by change in the Montgomery-Asberg Depression Rating Scale (MADRS). Data show that MIN-117 at the 0.5 milligrams (mg) daily dose had an effect size (magnitude of difference) as compared to the placebo group of 0.23 while the 2.5 mg daily dose had an effect size of 0.33. This magnitude of effect size is similar to those observed with currently marketed antidepressants. Improvement in MADRS with MIN-117 against placebo was observed at two weeks. Furthermore, data also show that 24 percent of the patients treated with 2.5 mg of MIN-117 achieved remission as prospectively defined.

Both doses of MIN-117 demonstrated a favorable tolerability profile, and the incidence and types of side effects did not differ significantly between the MIN-117 group and the placebo group. No unexpected adverse events were reported. Preliminary analysis shows that treatment with MIN-117 is not associated with cognitive impairment, sexual dysfunction, suicidal ideation or weight gain.

Pharmacodynamic measurements based on sleep recordings show that MIN-117 preserved sleep continuity and architecture and therefore is not expected to have detrimental effects on rapid eye movement (REM) sleep distribution and duration unlike most marketed antidepressants.

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“We believe these results show a meaningful clinical benefit and support further development of MIN-117, an antidepressant with a differentiated mechanism of action and a favorable tolerability profile,” said Dr. Remy Luthringer, president and chief executive officer of Minerva. “These promising results, combined with the drug’s distinctive pharmacology, lay the foundation to potentially address unmet needs not currently served by existing therapies in the treatment of mood disorders and other central nervous system indications.”

**About this study** (<https://www.clinicaltrialsregister.eu>, EudraCT Number: 2015-000306-18)

This study was a four-arm, parallel-group, randomized double-blind, placebo- and positive-control trial which tested two daily administered doses of MIN-117: 0.5 mg and 2.5 mg. The study included 84 patients (21 per arm) with moderate to severe MDD in four European countries. The goals of the trial were to test efficacy, safety and tolerability of MIN-117 over six weeks of treatment. The antidepressant paroxetine was used as an active control and confirmed assay sensitivity. Change on the MADRS, a scale measuring severity of depression, was used as the main outcome measurement. As established prospectively in the statistical analysis plan, this trial was designed for signal detection and effect size estimation. As such, the study was not powered to demonstrate statistically significant differences between MIN-117 and placebo.

#### **About Major Depressive Disorder**

Major depressive disorder (also referred to as major depression) is one of the most common mental disorders worldwide, with an estimated 350 million people affected. According to the World Health Organization, it is the leading cause of disability worldwide and a major contributor to the overall global disease burden. In the U.S. in 2014, an estimated 15.7 million adults aged 18 or older, representing 6.7 percent of all adults, had at least one major depressive in the past. Shortcomings of many current antidepressant therapies include a large number of treatment non-responders, delayed onset of action, sexual dysfunction and weight gain, all potentially leading to poor compliance with therapy.

#### **About Minerva Neurosciences**

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