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 18, 2019

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 **Suite 286** **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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**NERV**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events.

On December 18, 2019, Minerva Neurosciences, Inc. (the "Company") issued a press release providing details of the Company's results from a Phase 2b clinical trial of MIN-117. A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated December 18, 2019.

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/ Geoffrey Race
Name: Geoffrey Race
Title: Executive Vice President, Chief Financial Officer and Chief Business Officer

Date: December 18, 2019

Exhibit 99.1

Contact:

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

FOR IMMEDIATE RELEASE

MINERVA NEUROSCIENCES REPORTS TOPLINE RESULTS FROM PHASE 2B TRIAL OF MIN-117 IN MAJOR DEPRESSIVE DISORDER

- **MIN-117 study did not meet its primary (MADRS) and key secondary (HAM-A) endpoints**
- **MIN-117 was generally well-tolerated with a safety profile comparable to placebo**
- **Company to host conference call at 5:00 p.m. today (dial-in information below)**

Waltham, MA, December 18, 2019 – Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, announced today the Phase 2b trial of MIN-117 in adult patients suffering from moderate to severe major depressive disorder (MDD) and presenting with symptoms of anxious distress failed to meet its primary and key secondary endpoints.

Neither dose of MIN-117 tested in this trial showed a statistically significant separation from placebo on the reduction in the symptoms of MDD over the 6-week treatment period as measured by the change in the Montgomery–Åsberg Depression Rating Scale (MADRS). In addition, neither dose showed a statistically significant separation from placebo on the key secondary endpoint, reduction of symptoms of anxiety as measured by Hamilton Anxiety Rating Scale (HAM-A) over the 6-week treatment period. Patients treated with the 2.5 mg dose experienced an improvement of 1.6 points compared to placebo at Week 2 (p£ 0.029). No other statistically significant separation from placebo on HAM-A was observed.

MIN-117 was generally well tolerated, and the incidence of patients who reported treatment emergent adverse events over the duration of 6 weeks of treatment and 2 weeks of follow-up were 37% for the 2.5 mg, 39% for the 5 mg, and 38% for placebo. Only headaches were reported at ³5% in this study at 12% for both the 2.5 and 5 mg, and 7% for placebo. There were no deaths, and only 5 patients in total discontinued from the study due to TEAE (2 for 2.5 mg, 1 for 5 mg, and 2 for placebo).

“We are obviously disappointed with the results despite the trial having been very well executed,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “We express our sincere appreciation to all of the patients, the investigators and their staff who participated in this trial. At present, we have no plans for further clinical development of the molecule in MDD.”

Conference call

Minerva will hold a conference call and live audio webcast on December 18, 2019 at 5:00 p.m. Eastern Time. To participate, please dial (877)-312-5845 for domestic callers or (765) 507-2618 for international callers and refer to conference ID number 3296395. The live webcast can also 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 this study (www.clinicaltrials.gov Identifier NCT03446846)

This study was a 6-week, 3-arm, randomized, double-blind, placebo-controlled trial to investigate the safety and efficacy of MIN-117 in adult patients. 360 patients were randomly assigned to 1 of 3 treatment arms, including placebo, 5.0 mg. MIN-117 or 2.5 mg. MIN-117, in a 2:1:1 ratio. Patients enrolled in this study were diagnosed with moderate or severe MDD with anxious distress and without psychotic features. The study design had 3 phases: a screening phase of up to 3 weeks (including washout), a 6-week double-blind treatment phase, and a post-study follow-up visit. 40 sites in the U.S. and Europe participated in the trial.

The primary efficacy endpoint was the change in MADRS total score from baseline (the start of double-blind treatment) to the end of the double-blind treatment period (week 6). The primary comparisons were between each MIN-117 dose group and the placebo group. Secondary efficacy evaluations include the HAM-A, CGI-S, and CGI-I, as well as safety over six weeks of treatment.

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: roluperidone (MIN-101), in clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and Major Depressive Disorder (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 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 scope of future clinical trials and results of clinical trials with roluperidone and the further clinical development of MIN-117. 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 roluperidone or seltorexant 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; 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, 2019, filed with the Securities and Exchange Commission on November 4, 2019. 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.