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): February 28, 2022

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 February 28, 2022, Minerva Neurosciences, Inc. issued a press release announcing that the results from the Phase 3 clinical trial of roluperidone to treat negative symptoms in patients with schizophrenia have been published in Schizophrenia Bulletin. A copy of this press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Minerva Neurosciences, Inc. dated February 28, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: President

Date: February 28, 2022

FOR IMMEDIATE RELEASE

Minerva Neurosciences Announces Publication of Roluperidone Phase 3 Study Results in *Schizophrenia Bulletin*

Trial Results Confirm the Potential of Roluperidone To Treat Negative Symptoms and Improve Everyday Functioning in Patients with Schizophrenia

WALTHAM, Mass. – February 28, 2022 – (Globe Newswire) 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 results from the Phase 3 clinical trial of roluperidone to treat negative symptoms in patients with schizophrenia have been published in *Schizophrenia Bulletin*. The study authors conclude that this study confirms the potential of roluperidone to treat the negative symptoms in individuals with schizophrenia as well as improve everyday functioning.

The publication, entitled, "Efficacy and Safety of Roluperidone for the treatment of negative symptoms of schizophrenia," reports on the Phase 3 placebo-controlled multi-national trial of roluperidone, a compound with antagonist properties for 5-HT_{2A}, $sigma_2$ and α_{1A}-adrenergic receptors, targeting negative symptoms in patients with schizophrenia. The goal of the trial was to confirm the findings of a previous Phase 2 trial with a similar patient population and methodology that had demonstrated roluperidone superiority over placebo. The Company previously disclosed results of the Phase 3 trial of roluperidone in May 2020 and open-label results in May 2021.

The Phase 3 study included 513 patients with schizophrenia with moderate to severe negative symptoms. Study patients were administered either 32 mg/day of roluperidone, 64 mg/day of roluperidone, or placebo for 12 weeks. The primary endpoint was the PANSS-derived Negative Symptom Factor Score (NSFS) and the key secondary endpoint was Personal and Social Performance scale (PSP) total score.

The study found that NSFS scores improved (were lower) for patients receiving roluperidone 64 mg compared to placebo. The intent-to-treat (ITT) analysis data set ($p \leq 0.064$) marginally missed statistical significance, but reached nominal significance ($p \leq 0.044$) for the modified-ITT (m-ITT) data set. Changes in PSP total score were statistically significantly better on roluperidone 64 mg compared to placebo for both ITT and m-ITT ($p \leq 0.021$ and $p \leq 0.017$, respectively).

About roluperidone

On November 3, 2021, Minerva Neurosciences announced that the U. S. Food and Drug Administration (FDA) denied the company's request for a pre-NDA meeting for roluperidone and responded that a Type C guidance meeting would be more appropriate to discuss the evidence for use of roluperidone as

monotherapy for the treatment of negative symptoms in schizophrenia. A Type C meeting is scheduled. Subject to the timing of and feedback from the FDA, Minerva continues to plan for the submission of a New Drug Application (NDA) in the first half of 2022.

On September 30, 2021, the Company completed and announced results from a pivotal bioequivalence study comparing the roluperidone formulations used in its late-stage Phase 2b and Phase 3 trials and the planned commercial formulation. The planned commercial formulation was tested under both fasted and fed conditions. The study met key pharmacokinetic (PK) objectives, and the data demonstrate bioequivalence across the various formulations.

About Schizophrenia and Negative Symptoms

Schizophrenia is a chronic, severe and debilitating type of mental illness characterized by distortions in thinking, perception, emotions, language, sense of self and behavior. Schizophrenia affects 20 million people worldwide. (World Health Organization).

Negative symptoms can cause individuals with schizophrenia to withdraw from society, become disinterested or unable to complete tasks or feel pleasure. Negative symptoms are characterized by five constructs: blunted affect, alogia, avolition, anhedonia, and asociality (Marder and Galderisi, 2017).

Negative symptoms are the main cause of the poor functional outcome of patients suffering from schizophrenia (Harvey et al., 2020) and may also be one of the main reasons ultrahigh risk adolescents may develop full blown schizophrenia (Gomes and Grace, 2017). There are currently no treatments approved for negative symptoms of schizophrenia.

About Minerva Neurosciences

Minerva Neurosciences, Inc. (Nasdaq: NERV) is a clinical-stage biopharmaceutical company focused on developing product candidates to treat central nervous system (CNS) diseases. Our goal is to transform the lives of patients with improved therapeutic options. Minerva's portfolio of compounds includes roluperidone (MIN-101), in clinical development for negative symptoms of schizophrenia, and MIN-301, for Parkinson's disease. For more information, please visit our website.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements. 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, but not limited to, statements herein with respect to the timing and outcomes of future interactions with regulatory bodies, including the U.S. Food and Drug Administration; 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, the risk that trials and studies may be delayed and may not have satisfactory outcomes; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; whether roluperidone 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 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; unexpected litigation or other dispute; and the impacts of the COVID-19 pandemic on our business 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, 2021, filed with the Securities and Exchange Commission on November 8, 2021. 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.

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For more information:

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