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): August 22, 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 August 22, 2022, Minerva Neurosciences, Inc. (the "Company") issued a press release announcing that it has submitted a New Drug Application to the U.S. Food and Drug Administration for roluperidone for the treatment of negative symptoms in patients with schizophrenia. A copy of this press release is attached hereto as Exhibit 99.1 and is 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 August 22, 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: August 22, 2022

Exhibit 99.1

Minerva Neurosciences Submits New Drug Application to FDA for Roluperidone for the Treatment of Negative Symptoms in Patients with Schizophrenia

WALTHAM, Mass. – August 22, 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 the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for roluperidone for the treatment of negative symptoms in patients with schizophrenia. The roluperidone clinical development program aims to provide effective treatment for negative symptoms of schizophrenia, a significant unmet medical need in a large patient population.

"We believe that roluperidone may represent a new therapeutic option to treat patients with negative symptoms of schizophrenia for which there are currently no approved therapies in the United States. While positive symptoms of schizophrenia are generally well managed with antipsychotics, negative symptoms are often the main burden of illness and can impact the patients' quality of life as a result of disabilities caused by impaired vocational and social skills," said Remy Luthringer, Executive Chairman and Chief Executive Officer. "We would like to express our sincere appreciation and thanks to all the patients, caregivers and the investigators and their staff who participated in the roluperidone clinical studies. We have been in dialogue with the FDA following our Type C meeting in March 2022, and we look forward to working with the FDA as it evaluates the NDA."

NDA content:

The NDA submission is supported by results from two late-stage, well-controlled studies in patients with moderate to severe negative symptoms and stable positive symptoms of schizophrenia (Studies MIN-101C03 and MIN-101C07). Both studies were planned to constitute the bulk of evidence of roluperidone's effectiveness for the indication of treating negative symptoms of schizophrenia. This plan relied on both studies having the same overall study design: both were multicenter, multinational, randomized, double-blind, placebo-controlled, parallel-group studies in which patients received either 32 mg or 64 mg doses of

roluperidone. In both studies, if patients were taking antipsychotic treatments, they were discontinued and a washout period of two days was implemented before beginning the assigned study treatment. Both studies capture comparative placebo-controlled data through their 12-week double-blind period. Both studies also provide long-term exposure data regarding the safety and tolerability of roluperidone, and efficacy based on blinded doses of roluperidone, specifically intended to demonstrate the maintenance of improvement in negative symptoms and the low rate of worsening of positive symptoms following 24-week (Study MIN-101C03) and 40-week (Study MIN-101C07) Open Label (OL) periods. With the exception of the duration of the OL period, these two studies were nearly identical with respect to patient population and main assessment tools (Positive and Negative Syndrome Scale (PANSS), Personal and Social Performance Scale (PSP), Clinical Global Impression (CGI)). As such, the data from these studies are the basis for the decision to submit the application at this stage of development as we believe they provide sufficient data to support the long-term safety and efficacy in adults in an area of high unmet medical need.

Minerva is seeking approval for the 64 mg dose of roluperidone and results described hereafter are for the 64 mg dose only.

Results of Study MIN-101C03 supported the primary hypothesis that after 12 weeks of treatment, roluperidone is superior to placebo in reducing negative symptoms of schizophrenia. In the primary efficacy analysis, 64 mg roluperidone resulted in a statistically significant reduction of negative symptoms of schizophrenia as measured by PANSS Pentagonal Structured Model Negative score (PSM) ($p \leq 0.0036$). A post hoc analysis of the change from Baseline to Week 12 in the PANSS Marder's Negative Symptoms Factor Score (NSFS) also demonstrated a statistically significant difference for 64 mg roluperidone compared with placebo ($p \leq 0.001$). Statistically significant improvements with 64 mg roluperidone compared with placebo after 12 weeks of the Double Blind (DB) period were also seen for multiple secondary/exploratory efficacy analyses. Further improvements in the NSFS were also seen during the 24-week OL period.

The superiority of roluperidone over placebo was also demonstrated in Study MIN-101C07. Although the primary analysis (intent-to-treat (ITT)) of change from Baseline in the NSFS to Week 12 for roluperidone compared to placebo marginally missed statistical significance ($p \leq 0.064$), the results were quantitatively superior for 64 mg roluperidone treatment. Furthermore, the analysis of the modified intent-to-treat (mITT) population (mITT data set excludes data from one clinical site with implausible results for the 17 patients recruited at this site) demonstrated a nominal statistically significant improvement in the NSFS for 64 mg roluperidone compared to placebo ($p \leq 0.044$). In addition, statistically significant improvements (unadjusted) in the NSFS from Baseline were seen as early as Weeks 4 and 8 for 64 mg roluperidone

compared to placebo for both the ITT and the mITT populations. PSP Total score (key secondary endpoint measuring vocational and social skills) reached statistical significance for both ITT ($p \leq 0.021$) and mITT ($p \leq 0.017$) populations. Further improvements in the NSFS and PSP Total score were also seen during the 40-week OL period.

Additional information submitted to FDA following Type C meeting on March 2, 2022

On April 7, 2022, Minerva announced that it had received the official meeting minutes from the Type C meeting with FDA held on March 2, 2022, in which the development of roluperidone for the treatment of negative symptoms in schizophrenia was discussed. Four main topics (listed below) were highlighted by the FDA for which they requested input and further clarification from Minerva. FDA proposed to keep an open dialogue moving towards the NDA submission. Following the meeting, Minerva provided additional data to address;

1. The potential impact of roluperidone administration on the efficacy and safety of antipsychotic drugs. More specifically, the Division wanted reassurance that those patients administered roluperidone who manifest worsening of schizophrenia symptoms and in the opinion of the clinician/investigators need treatment with antipsychotics, do not experience a diminished benefit of the antipsychotic treatment or unexpected adverse effects.
2. The comparability of US and non-US schizophrenia patients. More specifically, the Division wanted to be reassured that data collected in MIN-101C03 in non-US patients is applicable to US patients
3. Supporting statistical evidence of efficacy of roluperidone on negative symptoms.
4. The ability of clinicians to identify patients who might benefit from roluperidone

Minerva believes that the additional data and analyses shared with the FDA further demonstrate that roluperidone satisfies the criteria for FDA approval and can address the unmet medical need in patients with schizophrenia whose positive symptoms have been stable for several months and moderate to severe negative symptoms persist.

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 ultra-high risk adolescents may develop full blown schizophrenia (Gomes and Grace, 2017). There are currently no treatments approved for negative symptoms of schizophrenia in the US.

Minerva believes that research continues to emerge indicating that there is a large subgroup of patients with schizophrenia who have moderate to severe primary negative symptoms and minimal positive symptoms (Galderisi 2021) and have a low risk of worsening of positive symptoms even in the absence of antipsychotic treatments (Harrow 2013; Moilanen 2016; Murray 2016; Wils 2017; Wunderink 2013; Landolt 2016). The unmet medical need for treatments for this subgroup of patients is large.

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 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. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words.

Forward-looking statements in this press release include, but are not limited to, statements with respect to the clinical development of roluperidone as monotherapy for the treatment of negative symptoms of schizophrenia; the potential benefits of roluperidone as monotherapy for the treatment of negative symptoms of schizophrenia or any other indication; the adequacy and efficacy of our clinical trials and studies with roluperidone, and the sufficiency of the data from such trials and studies to support marketing application; our interpretation of the feedback from the U.S. Food and Drug Administration (FDA); the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the FDA; 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 our interactions with the FDA will have satisfactory outcomes; whether the FDA will support and accept an NDA submission for roluperidone; whether and when, if at all, our NDA for roluperidone will be approved by the FDA; whether the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful; whether the FDA may meet expected review timelines for our NDA; whether roluperidone will be successfully marketed if approved; 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. Other factors that may cause our actual results to differ from those expressed or implied in the forward-looking statements in this press release are identified 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 June 30, 2022, filed with the Securities and Exchange Commission on August 9, 2022. 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 expressly disclaim any obligation to update any forward-looking statements, except as required by law.

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