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): May 1, 2023

Minerva Neurosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-36517**	**26-0784194**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer ID Number)**

1500 District Avenue, Burlington, MA 01803
(Address of principal executive offices) (Zip Code)

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

Not Applicable
(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 Capital 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 May 1, 2023, Minerva Neurosciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration filed the Company's New Drug Application for roluperidone for the treatment of negative symptoms in patients with schizophrenia on April 27, 2023. 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 May 1, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

Dated: May 1, 2023

By: /s/ Geoffrey Race
Name: Geoffrey Race
Title: President

Exhibit 99.1

FOR IMMEDIATE RELEASE

Minerva Neurosciences Announces the NDA Filing for Roluperidone for the Treatment of Negative Symptoms in Schizophrenia

FDA grants appeal and files NDA

BURLINGTON, Mass. – May 1, 2023 – (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 U.S. Food and Drug Administration (FDA) filed the Company's New Drug Application (NDA) for roluperidone for the treatment of negative symptoms in patients with schizophrenia on April 27, 2023. The decision to file the NDA follows the Company's request for formal dispute resolution and appeal of FDA's October 2022 refuse to file letter. The issues cited in the refuse-to-file decision included those discussed at the type C meeting in April 2022. In granting the appeal, the FDA deciding official agreed with the Company that the issues cited in the refuse-to-file decision should be considered during FDA's review of the NDA.

"We thank the FDA for its thoughtful review and consideration of our materials submitted during the formal dispute resolution process. We look forward to continuing to work with the FDA with the ultimate goal of obtaining approval of roluperidone as the first approved treatment for negative symptoms of schizophrenia for the benefit of patients, their families, caregivers, and physicians," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

"Negative symptoms are a major source of disability in people with schizophrenia and there have been no approved treatments to date. An approved treatment for negative symptoms could revolutionize the treatment of schizophrenia and would certainly have a major impact on the quality of life of the millions of people affected with this disease," said Dr. Philip Harvey, Leonard M. Miller Professor of Psychiatry and Behavioral Sciences and Director of the Division of Psychology at the University of Miami Miller School of Medicine.

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).

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 include, but are not limited to, statements herein with respect to the regulatory progress and therapeutic potential of roluperidone for the treatment of negative symptoms in patients with schizophrenia. 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 the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain regulatory approval; 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 and corporate objectives on terms acceptable to us; general economic conditions; and other factors that are described under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 8, 2023. 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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