

**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): November 3, 2021**

**Minerva Neurosciences, Inc.**

(Exact name of registrant as specified in its charter)

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

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

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

**1601 Trapelo Road**  
**Suite 286**  
**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)

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:

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

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 November 3, 2021, Minerva Neurosciences, Inc. issued a press release announcing that the U.S. Food and Drug Administration has denied its request for a pre-NDA meeting for roluperidone and recommended that a Type C guidance meeting would be more appropriate to discuss the evidence for use of roluperidone as monotherapy. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release of Minerva Neurosciences, Inc. dated November 3, 2021.</a>
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: November 3, 2021

FOR IMMEDIATE RELEASE



**Minerva Neurosciences Announces FDA Recommendation for Type C Meeting to Discuss Evidence for Use of Risperidone as Monotherapy for the Treatment of Negative Symptoms in Patients with Schizophrenia in Advance of Potential NDA Submission**

Waltham, Mass. – November 3, 2021 – (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) has denied the company’s request for a pre-NDA meeting for risperidone and responded that a Type C guidance meeting would be more appropriate to discuss the evidence for use of risperidone as monotherapy. Subject to the timing of and feedback from the FDA at a Type C guidance meeting, which the Company plans to request, the Company has not changed its previously announced projected timeline for submission of the NDA in the first half of 2022.

Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva commented, “We thank the FDA for suggesting a Type C meeting to discuss risperidone as a monotherapy for the treatment of negative symptoms in patients with schizophrenia. There are currently no approved drugs in the U.S. for the treatment of the negative symptoms of schizophrenia. There is a large percentage of patients with schizophrenia who suffer predominantly negative symptoms.”

**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 risperidone (MIN-101), in clinical development for negative symptoms of schizophrenia, and MIN-301, in pre-clinical development 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 are not limited to, statements herein with respect to the timing and scope of clinical trials and regulatory review and results and outcomes of such clinical trials and regulatory review with risperidone (MIN-101); the clinical and therapeutic potential of this compound; the timing and outcomes of future interactions with U.S. and foreign 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, whether risperidone 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; 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 June 30, 2021, filed with the Securities and Exchange Commission on August 2, 2021. Copies of reports filed with the SEC are posted on our [website](#). 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:

Investor inquiries:

**Fred Ahlholm**

CFO, Minerva Neurosciences

[fahlholm@minervaneurosciences.com](mailto:fahlholm@minervaneurosciences.com)

Media Inquiries:

**Helen Shik**

Principal, Shik Communications LLC

[helen@shikcommunications.com](mailto:helen@shikcommunications.com)