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 15, 2017

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 284** **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))

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 15, 2017, Minerva Neurosciences, Inc. (the "Company") issued a press release providing details of the Company's MIN-101 end-of-Phase 2 meeting with the U.S. Food and Drug Administration, and a press release providing an update on the Company's MIN-101 Phase 3 design and development strategy. A copy of the above referenced press releases are filed as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K.

The Company is also filing the investor presentation slides attached as Exhibit 99.3 to this Current Report on Form 8-K which the Company may use from time to time with investors and analysts. The presentation will also be available in the investor relations section of the Company's website.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated May 15, 2017
99.2	Press Release of the Company dated May 15, 2017
99.3	Presentation of the Company dated May 16, 2017

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/ Mark S. Levine
Name: Mark S. Levine
Title: Senior Vice President, General Counsel and Secretary

Date: May 15, 2017

INDEX OF EXHIBITS

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Exhibit 99.1

Contact:

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

FOR IMMEDIATE RELEASE

MINERVA ANNOUNCES OUTCOME OF END-OF-PHASE 2 MEETING WITH FDA

Pivotal Phase 3 trial design to include monotherapy administration of MIN-101 and primary endpoint of improvement in negative symptoms of schizophrenia

Planned initiation of MIN-101 Phase 3 development in second half of 2017

Waltham, MA, May 15, 2017 – Following a recent "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA), 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 its plans to initiate Phase 3 development of MIN-101, a drug targeting negative symptoms in schizophrenia patients. A pivotal Phase 3 trial with MIN-101 is expected to be initiated in the second half of 2017.

The Phase 3 trial design will be a 12-week, double-blind, randomized, placebo-controlled, monotherapy study testing two doses of MIN-101 in patients with negative symptoms and a diagnosis of schizophrenia. To be eligible for this study, patients will be required to have stable negative and positive symptoms over several months prior to enrollment, with a specified minimum threshold baseline score on the Positive and Negative Syndrome Scale (PANSS) negative sub-scale.

After the double-blind phase, patients may enter a 36-week open label extension phase in which all patients will receive active treatment. This multi-center, international trial is expected to enroll approximately 500 patients at approximately 60 clinical sites across the U.S. and Europe.

The primary endpoint will be improvement in negative symptoms at 12 weeks as measured by the PANSS Marder negative factor score, a widely recognized instrument for quantifying severity of negative symptoms. Secondary efficacy endpoints will include the Clinical Global Impression of Severity (CGI-S) scale and Personal and Social Performance (PSP) total score. The overall design of the planned Phase 3 trial is similar to the Phase 2b trial completed in 2016, in which improvement was observed in schizophrenic patients with negative symptoms treated with MIN-101 compared to placebo.

The Company shared pre-clinical and clinical efficacy and safety data at the FDA meeting, and safety and tolerability of MIN-101 will continue to be assessed during the duration of the Phase 3 trial, including cardiac function via electrocardiograms (ECGs). Discontinuation criteria based on PANSS and cardiac electrophysiological criteria will be incorporated into the study protocol.

"Minerva is finalizing its plan for the Phase 3 development of MIN-101, an innovative investigational treatment for schizophrenia, following our recent meeting with the FDA," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Our discussion with the agency has helped to confirm

our Phase 3 trial design, which is similar to our previous Phase 2b trial design. We believe that positive data from the Phase 3 trial, along with the positive data from the Phase 2b trial, may form the basis for the future submission of a New Drug Application for MIN-101 to the FDA."

"The constructive feedback from the agency supports the further development of MIN-101 for schizophrenia," said Dr. Philip D. Harvey, Leonard M. Miller Professor of Psychiatry and director of the Division of Psychology at the University of Miami Miller School of Medicine. "Negative symptoms currently continue to represent a significant unmet need and contribute substantially to poor quality of life and functional outcomes for the large worldwide population of patients with this disease."

Updates and further details regarding the Phase 3 trial, including anticipated timing of recruitment, participating centers and investigators will be provided later this year and posted on www.clinicaltrials.gov.

About schizophrenia and the impact of negative symptoms

Schizophrenia remains among the top ten disabling conditions worldwide for young adults and affects more than 21 million people worldwide. According to Datamonitor, an independent market research firm, in 2016 approximately 3.3 million people suffered from schizophrenia in the United States, Japan and the five major European Union markets of France, Germany, Italy, Spain and the United Kingdom.

Although positive psychotic symptoms are characteristic of schizophrenia, negative symptoms constitute one of the main sources of burden of illness, represent an important treatment target and are a major cause of the poor vocational and social capabilities of these patients. These symptoms, which include a-motivation, avolition, lack of initiative, and restricted personal interaction, are associated with poor psychosocial functioning.

In the majority of schizophrenia patients, acute positive symptoms remit due to treatment with antipsychotics (dopamine-blocking drugs) or spontaneously. Antipsychotic drugs also reduce the risk for recurrence of psychosis. However, many patients maintain remission of psychosis without antipsychotic dopamine blocking drugs. Nevertheless, they continue to suffer negative symptoms, for which no FDA-approved treatments are specifically indicated.

About MIN-101

MIN-101 is a drug candidate with equipotent affinities for sigma 2 and 5-hydroxytryptamine-2A (5-HT2A) and lower affinity at α1-adrenergic receptors. MIN-101 has no direct dopaminergic post-synaptic blocking effects, known to be involved in some side effects like extrapyramidal symptoms, sedation, prolactin increases and weight gain.

The Phase 2b trial with MIN-101, announced in 2016 and presented at the annual meeting of the American College of Neuropsychopharmacology, met its primary endpoint of statistically significant improvement in negative symptoms as measured by the PANSS pentagonal structure model and in the higher dose showed statistically significant benefit in multiple secondary endpoints that included general psychopathology.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, in clinical development for schizophrenia; MIN-117, in clinical

development for major depressive disorder (MDD); MIN-202 (JNJ-42847922), in clinical development for insomnia and 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 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 results of future clinical milestones with MIN-101, including the planned Phase 3 trial of MIN-101, the timing and scope of future clinical trials and results of clinical trials with this compound; the potential for a single Phase 3 trial with supportive Phase 2b results to support the basis for an NDA; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize MIN-101; the sufficiency of our current cash position to fund our operations; 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 MIN-101 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 the results of future clinical trials of MIN-101, if any, will be consistent with the results of past clinical trials; whether MIN-101 will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our co-development agreements; 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 March 31, 2017, filed with the Securities and Exchange Commission on May 4, 2017. 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.

Exhibit 99.2

Contact:

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

FOR IMMEDIATE RELEASE

MINERVA PROVIDES UPDATE ON PHASE 3 DESIGN AND DEVELOPMENT STRATEGY FOR MIN-101

Advancing a new potential therapeutic paradigm for the treatment of negative symptoms, a key unmet need in schizophrenia and other brain diseases

Company to host conference call on May 16, 2017 at 10:30 a.m. eastern time

Waltham, MA, May 15, 2017 – 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 plans for its Phase 3 and Phase 4 clinical development of MIN-101, a drug targeting negative symptoms in schizophrenia patients. Following a recent "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA), the Company's next step is the planned initiation of a pivotal Phase 3 trial with MIN-101 in the second half of 2017.

"We are very excited to be taking MIN-101 into a pivotal Phase 3 trial, which has the potential to identify a new approach to the treatment of schizophrenia and improve the quality of life for millions of patients," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Our development strategy for MIN-101 is driven by the recognition that, while positive symptoms are present intermittently and are a hallmark of early schizophrenia, negative symptoms persist and worsen over the lifetimes of the majority of schizophrenic patients, severely limiting their social and vocational reintegration over the longer term. No drugs are currently approved to treat the negative symptoms of schizophrenia or negative symptoms present in other conditions, including developmental disorders, affective disorders and neurodegenerative disorders."

Data from the Company's Phase 2b trial with MIN-101 have informed the design of the Phase 3 trial. Key findings from the Phase 2b trial include observations of a direct effect on negative symptoms (rather than an indirect or pseudo effect linked to improvements in other symptoms and/or a different side effect profile). The data also support the durability of this effect through the entire 36-week duration of the trial, which included a 12-week double-blind, placebo-controlled core phase and a 24-week, open-label extension phase. The specificity of MIN-101's therapeutic effects on negative symptoms was validated by the stability of positive symptoms observed over the entire duration of treatment and a side effect profile comparable to placebo, particularly as it relates to extra-pyramidal symptoms (EPS). The Company believes that the unique pharmacological profile of MIN-101 (sigma 2 and serotonin $5HT_{2a}$ receptor antagonism) and the absence of direct binding to post-synaptic dopamine receptors may explain its specific effects on negative symptoms.

Key elements of the Phase 2b trial that will be incorporated into the Phase 3 trial include:

- improvement in negative symptoms as the primary endpoint;
- monotherapy administration of MIN-101 and no co-administration with atypical antipsychotics at any stage in the study;
- recruitment of patients with moderate-to-severe negative symptoms expressed as a specified minimum threshold baseline score on the Positive and Negative Syndrome Scale (PANSS) negative sub-scale; and
- a 12-week double-blind, randomized, placebo-controlled core phase followed by an open-label extension phase.

Two doses of MIN-101or placebo will be administered during the double-blind phase of the Phase 3 trial, which will last 12 weeks, followed by an optional 36-week extension phase in which all patients will receive MIN-101. Approximately 500 patients will be enrolled at approximately 60 clinical sites across the U.S. and Europe, with a significant number of patients recruited at U.S. sites. The Company believes that the efficacy data from the Phase 3 trial, if positive, in addition to the Phase 2b data, may form the basis for the future submission of a New Drug Application (NDA) for MIN-101 to the FDA. Furthermore, at the conclusion of the extension period of the Phase 3 trial, the overall number of patients exposed to MIN-101 since the initiation of its clinical development is expected to provide sufficient long-term safety data to support an NDA.

The primary Phase 3 trial endpoint of improvement in negative symptoms at 12 weeks will be measured by the PANSS negative sub-scale score using the Marder factor, a widely recognized instrument for quantifying severity of negative symptoms. The Marder negative sub-score is similar to the White negative sub-score used in the Phase 2b trial. The two factors differ from each other in that the Marder score has eliminated four items and added one on active social avoidance (G16 item). The Company is employing the Marder scale because this item has been shown to be well correlated with patients' overall functional outcome.

The Company's Phase 3 trial design is intended to replicate the experience of "real world" clinical practice in schizophrenia. Many patients are dissatisfied and not well served by continuous antipsychotic treatment as evidenced by poor compliance with medications. Recent scientific literature points toward the fact that indefinite antipsychotic maintenance treatment in schizophrenic patients (provided by post-synaptic blockade of dopamine receptors) may be responsible for poor long term functional outcomes in addition to well described side effects, including EPS, weight gain, sedation and prolactin increase. In summary, the Phase 3 trial will seek to confirm clinically meaningful effects on patients' negative symptoms and to determine whether patients can stay stable in terms of positive symptoms without experiencing the adverse effects of antipsychotics.

Treatment of the positive symptoms of schizophrenia represents a large market estimated at more than $6.2 billion in 2016. Epidemiological studies suggest that an estimated 60 percent of schizophrenia patients present with negative symptoms, which are the basis of poor functional outcome and thus represent a significant unmet medical need and burden for patients, families and society.

In Phase 4 development, the Company plans to conduct additional trials to expand the profile of MIN-101. These may potentially include a study comparing the rate of psychosis relapses in patients treated with MIN-101, standard of care with antipsychotics or placebo. In addition, the Company may conduct a trial in adolescents at high risk for schizophrenia who during the prodromal phase manifest negative symptoms.

While negative symptoms are a core component of schizophrenia and predict poor functional capacity, they are not specific to that disease but are also recognized as a hallmark of other diseases. These include neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, mood disorders, schizophrenia spectrum disorders and autism spectrum disorders. The Company plans to assess these indications as expansion options for MIN-101 in a development program beyond the planned Phase 3 study in schizophrenia.

Conference call information

The Company will host a conference call and live webcast tomorrow, May 16, 2017 at 10:30 a.m. Eastern Time to discuss its plans for Phase 3 development of MIN-101 and beyond. The topics outlined above will be addressed. To participate, please dial 800-263-8506 (domestic) or 719-457-2605 (international) and refer to conference ID # 1545954. Leading the call will be Dr. Remy Luthringer, president and chief executive officer of Minerva. Also participating will be key opinion leaders in the field of schizophrenia, including Dr. Philip Harvey, Leonard M. Miller Professor of Psychiatry and director of the Division of Psychology at of the University of Miami Miller School of Medicine, and Dr. Brian Kirkpatrick, chair of the Department of Psychiatry and Behavioral Sciences at the University of Nevada School of Medicine. Both Dr. Harvey and Dr. Kirkpatrick are internationally recognized for their work in the field of schizophrenia and negative symptoms, and they participated in the recent meeting between the FDA and Minerva as consultants to the Company.

The webcast can be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website beginning approximately two hours after the event for 90 days.

About schizophrenia and the impact of negative symptoms

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Exhibit 99.3

MIN-101 DEVELOPMENT UPDATE
POST EOP2 MEETING WITH FDA

May 16, 2017

Nasdaq: NERV

Forward-Looking Statement Safe-Harbor

MINERVA NEUROSCIENCES, INC.

This presentation contains forward-looking statements about Minerva Neurosciences 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 presentation, and involve certain risks and uncertainties. Forward-looking statements include, but are not limited to: the benefits, efficacy and safety of our new formulations; whether studies performed on analogs or backups of our compounds are a good predictor of the clinical efficacy of our compounds; statements with respect to the timing and results of future clinical milestones with MIN-101, including the planned Phase 3 trial of MIN-101; the timing and scope of future clinical trials and results of clinical trials with this compound; the potential for a single Phase 3 trial with supportive Phase 2b results to support the basis for an NDA; statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; our expectations regarding approval for our products by the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; estimates regarding the market potential for our products; financial projections and estimates and their underlying assumptions; and future performance. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. 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 MIN-101 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 the results of future clinical trials of MIN-101, if any, will be consistent with the results of past clinical trials; whether MIN-101 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our co-development agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for our therapeutic products; our ability to raise additional capital to fund our operations on terms acceptable to us; 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 March 31, 2017, filed with the Securities and Exchange Commission on May 4, 2017. Copies of reports filed with the SEC are posted on our website at www.minervaneurosciences.com. Our audience is cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we disclaim any obligation to update any forward-looking statements, except as required by law.

Phase 3 efficacy study: confirmatory study design (1)

MINERVA NEUROSCIENCES, INC.

- 3 months double-blind + 9 months open-label
- ~500 patients randomized 1:1:1 to two doses of MIN-101 vs placebo, mono-therapy
  - ✓ *Symptomatically stable patients for several months with moderate to severe negative symptoms (>20 PANSS negative), mild positive symptoms**
  - ✓ *Poor response to treatment in terms of social and vocational adjustment*
  - ✓ *Normal lab and VS; ECG; extensive CYP2D6 metabolisers*
- If patients are on antipsychotic medication, switch to MIN-101 without long wash-out periods so that the study mimics clinical practice

*** Depending on the threshold for functional disability and for severity of negative symptoms this represents approximately 60% of schizophrenia patients**

Phase 3 efficacy study: confirmatory study design (2)

MINERVA NEUROSCIENCES, INC.

- Primary outcome Marder cluster of negative symptoms
  - *(N1, N2, N3, N4, N6, G7, **G16**)*
- Secondary outcomes CGI and PSP
  - together with G16 will highlight effect on social functioning
- ~1/3 of the patients to be recruited in the US, with the remainder from EU
  - *~60 sites*
  - ***Topline results of the 3 month double-blind phase expected 1H 2019***
- The 12-month data (3 double-blind and 9 open-label) will show:
  - *The long term safety profile based on number of patients and time of exposure*
  - *The ability of MIN-101 to improve negative symptoms beyond 3 months and prevent worsening of positive symptoms as indicated in phase 2b*

Minerva believes that positive phase 3 data from this study along with the phase 2b data could be the basis for a NDA filing

Phase 3 efficacy study: Safety and tolerability aspects

MINERVA NEUROSCIENCES, INC.

- Vital signs
- ECGs (triplicate; centralized reading)
- Regular lab testing including prolactin
- Pharmacokinetics samples for MIN-101 levels & un-allowed treatments

Phase 3: Key activities in parallel to efficacy study

MINERVA NEUROSCIENCES, INC.

- Standard clinpharm studies for NDA, including:
  - DDI studies
  - tQt study
  - Population at risk (renal impaired patients)
- Complete carcinogenicity package
- CMC package
- Toxicological package completion*

*** 6 and 9 months toxicological package completed**

Other strategic considerations (1): Pediatric plan

MINERVA NEUROSCIENCES, INC.

- Conduct trial in Ultra High Risk adolescents (premorbid schizophrenia, early onset schizophrenia)
  - large population
  - predominant manifestation of negative symptoms
  - poor benefit/risk ratio of antipsychotics and major ethical dilemma
    - few subjects progress to psychosis hence, most are Rx with no benefit expected
    - therefore Rx must be safe and very well tolerated
    - low efficacy of D2 blockers and poor compliance
  - potential for additional 6 months of market exclusivity

Other strategic considerations (2): Phase 4, additional trials in schizophrenia

MINERVA NEUROSCIENCES, INC.

- Relapse prevention trials in non-acutely exacerbated patients
- Demonstrate better tolerability and improved patient satisfaction
  - No EPS and no metabolic AE compared to D2 blocker hence potential for
    - better compliance
    - lower stigmatization
    - better social and vocational reintegration

Other strategic considerations (3): Phase 4 trials in additional indications

MINERVA NEUROSCIENCES, INC.

- Schizophrenia spectrum disorder and DSM-5 recognized diagnostic category of socially and vocationally impaired individuals with considerable negative symptoms and no current Rx available

- Apathy and avolition in
  - brain degenerative disorders AD, PD, Frontal Dementia
  - Autism spectrum disorders
  - Post CVA
  - Post head concussion

- Partial recovery from major depression but residual apathy