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): June 24, 2019

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** **(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:

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 June 24, 2019, Minerva Neurosciences, Inc. (the "Company") issued a press release providing details of the Company's results from a Phase 2b clinical trial of seltorexant (MIN-202) in insomnia. A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated June 24, 2019.

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: Executive Vice President, Chief Financial Officer and Chief Business Officer

Date: June 26, 2019

Exhibit 99.1

Minerva Neurosciences Announces Achievement of Primary and Key Secondary Objectives in Phase 2b Clinical Trial of Seltorexant (MIN-202) in Insomnia

June 24, 2019

- **Primary endpoint, defined as Latency to Persistent Sleep (LPS) at Night 1, showed improvement with a p-value ≤0.001 after treatment with 10 and 20 mg doses of seltorexant**
- **Key secondary endpoint, defined as Wake After Sleep Onset over first 6 hours (WASO-6) at Night 1, showed improvement with a p-value ≤0.005 after treatment with 10 and 20 mg doses of seltorexant**
- **Treatment with 10 and 20 mg doses of seltorexant showed greater improvement compared to zolpidem in LPS and WASO-6**
- **Beneficial effects maintained over time**
- **Effects consistent in both adult and elderly patients**
- **Safety and tolerability profile comparable to placebo in both adults and elderly**
- **Potential first-in-class specific orexin-2 receptor antagonist for the treatment of insomnia**
- **Company to host conference call at 8:30 a.m. today (dial-in information below)**

WALTHAM, Mass., June 24, 2019 (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 results of a clinical trial (ISM2005) of seltorexant (MIN-202) in patients with insomnia disorder that demonstrated highly statistically significant ($p \leq 0.001$) and clinically meaningful improvement on LPS at Night 1, the primary endpoint of the study. The mean decrease from baseline at Night 1 in LPS was 15 minutes for placebo, 30 minutes for seltorexant 5 mg, 50 minutes for seltorexant 10 mg, and 48 minutes for seltorexant 20 mg.

For the key secondary endpoint, WASO-6 at Night 1, the mean improvement from baseline at Night 1 was 15 minutes for placebo, 23 minutes for seltorexant 5 mg, 43 minutes for 10 mg, and 45 minutes for 20 mg of seltorexant. Furthermore, multiple secondary endpoints were also improved versus placebo and standard of care zolpidem, which is available under the brand name Ambien.

Additional details are provided below.

“The findings from this study demonstrate that seltorexant significantly improves sleep induction and prolongs sleep duration,” said Professor Thomas Roth, Director of the Sleep Disorders and Research Center at Henry Ford Hospital. “The results also demonstrate that seltorexant showed a significantly greater improvement in these sleep parameters compared to zolpidem.

“In addition, the beneficial effects on LPS and WASO of seltorexant on elderly patients in the study, in conjunction with a favorable tolerability profile, suggest its potential benefit in the large and growing population of elderly patients whose prevalence of insomnia is higher than in younger patients, thus representing an important therapeutic option,” said Professor Roth.

Professor David Kupfer, Distinguished Professor Emeritus of Psychiatry at the University of Pittsburgh School of Medicine and board member of Minerva, said, “Based on these results and those from the recent MDD2001 study, observations of seltorexant include a clinically meaningful improvement in symptoms of depression in patients not responding adequately to first line therapies (SSRIs and SNRIs) and a clinically meaningful effect on insomnia in a wide age range of patients.

“The demonstration of a significant benefit across a broad spectrum of patients who suffer with depression and/or insomnia and who have not responded adequately to existing therapies points to a differentiated clinical profile and a new way to address an underserved patient population” added Professor Kupfer.

“Seltorexant is a specific orexin- 2 antagonist (SORA) rather than a dual orexin receptor antagonist (DORA) and consequently has a differentiated mechanism of action that may help address numerous psychiatric disorders,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “Unlike existing therapies, seltorexant is designed to mimic the natural sleep process by inhibiting the brain mechanisms that promote excessive wakefulness rather than by sedating patients through the activation of the neurotransmitters that promote sleep.”

About the ISM 2005 trial

Study design:

This multicenter, phase 2b, double-blind, randomized, parallel-group, active- and placebo-controlled, 17-day (2 weeks of active treatment) dose finding study was designed to evaluate the efficacy and safety of seltorexant in both adult (18 to 64 years old) and elderly (65 to 85 years old) subjects with insomnia disorder without psychiatric co-morbidity. The study enrolled a total number of 365 subjects, randomized in a 1:1:1:1:1 ratio to receive one of 5 treatments: placebo, seltorexant 5 mg, seltorexant 10 mg, seltorexant 20 mg and zolpidem (5 or 10 mg based on the local label). The randomization was stratified by region (United States/Europe and Japan) and age group (adult and elderly).

Efficacy was evaluated at Night 1 (first drug administration) and after 2 weeks of drug administration (Night 13). Safety was evaluated throughout the study duration.

Polysomnography (PSG), an objective measure of sleep, was used to evaluate the effect of seltorexant, placebo and zolpidem.

Primary and secondary objectives:

The primary objective was to evaluate the dose-response of three doses of seltorexant (5, 10 and 20 mg daily) compared to placebo using the primary endpoint, sleep onset as measured by LPS by PSG at Night 1 (first drug administration).

The key secondary objective was to assess the effect of seltorexant on the key secondary endpoint, WASO-6 by PSG at Night 1.

Other secondary objectives included:

1. To assess the effect of seltorexant on LPS and WASO-6 at Night 13.
2. To assess the effect of seltorexant compared to standard of care treatment zolpidem on both LPS and WASO-6 at Nights 1 and 13.

Overall safety and tolerability were evaluated throughout the study duration.

Both adult (18 to <65 years of age) and elderly (65 to 85 years of age) patients have been included in the study in order to better understand age dependent efficacy and tolerability of seltorexant and zolpidem.

Statistics:

The primary efficacy endpoint, LPS, was evaluated at a 1-sided significance level of 0.05 using the MCP-Mod (Multiple Comparison Procedure-Modeling) approach to test for dose-response. For all remaining statistical analyses of the primary efficacy endpoint and for all other secondary efficacy endpoints, mixed model for repeated measures (MMRM) or analysis of covariance (ANCOVA) with no multiplicity adjustment were performed. The primary and key secondary endpoints were log-transformed before the statistical analysis using ANCOVA/MMRM models. For all analyses other than MCP-Mod, 2-sided p-values are presented. When treatment comparisons resulted in significant p-values ($p \leq 0.050$), these are also presented below.

The pre-specified comparisons to zolpidem on both endpoints and the overall safety and tolerability are also included.

Results:

Of the 364 subjects that received study drugs, 32.4% were male. The mean (SD) age was 57.8 (SD = 12.4) years, ranging from 22 to 84 years. Subjects had a mean total insomnia severity Index (ISI) score of 20.2 at baseline, indicative of moderate to severe insomnia.

Primary endpoint:

All 4 pre-specified dose-response models showed a significant dose-response relationship in LPS at Night 1, where the adjusted 1-sided p-values were <0.001.

There was a significant separation from placebo of the 10 mg and 20 mg dose groups. The advantage in least squares (LS) mean on changes from baseline of the seltorexant dose groups over placebo at Night 1 were: 16.4 minutes for the 5 mg, 32.2 minutes for the 10 mg ($p \leq 0.001$), and 36.6 minutes for the 20 mg ($p \leq 0.001$). Advantages over placebo were also observed at Night 13: 5.2 minutes for the 5 mg, 28.6 minutes for the 10 mg ($p \leq 0.001$), and 21.0 minutes for the 20 mg ($p \leq 0.001$).

Secondary endpoints:

WASO-6 at Night 1 showed an advantage in LS mean on change from baseline of the seltorexant dose groups over placebo of: 14.6 minutes for the 5 mg, 28.6 minutes for the 10 mg ($p \leq 0.005$), and 28.6 minutes for the 20 mg ($p \leq 0.001$). Advantages over placebo were also observed at Night 13: 6.5 minutes for the 5 mg, 16.1 minutes for the 10 mg, and 21.5 minutes for the 20 mg ($p \leq 0.002$).

WASO-6 was selected as the key secondary endpoint since seltorexant has a short half-life, and in previous studies some subjects awoke after 6-7 hours and did not feel the need for additional sleep. Moreover, WASO-6 is often considered to be a clinically relevant measure in sleep trials, since working adults commonly do not elect to remain in bed asleep for an entire 8-hour period.

Seltorexant 20 mg showed a greater improvement compared to zolpidem for LPS at both Night 1 (10.5 minutes, $p \leq 0.010$) and Night 13 (12.1 minutes, $p \leq 0.036$), while 10 mg only separated at Night 13 (19.6 minutes, $p \leq 0.021$). For WASO-6, the 20 mg dose showed significantly greater improvement compared to zolpidem at Night 13 (11.6 minutes, $p \leq 0.019$). Zolpidem immediate release (IR), which was administered as 5 or 10 mg according to the country-by-country label, was chosen as active comparator and showed superiority to placebo for both LPS and WASO-6 at Night 1 but not Night 13, demonstrating a known decrease of effect of zolpidem over time.

Analyses of the LPS and WASO-6 were also performed by subgroups, including age (adults and elderly), and overall these analyses were consistent with the primary analysis. Additionally, the LPS results were similar between the 2 age subgroups. WASO-6 had a better response in the elderly (all 3 doses significantly separated from placebo) compared to the adult population (only the 20 mg group significantly separated from placebo).

Similar to previous clinical trials, seltorexant showed a good safety and tolerability profile in both adult and elderly patients. Overall seltorexant was well tolerated, with treatment-emergent adverse events (TEAEs) similar to those observed in previous studies. The overall incidence of adverse events in the seltorexant treatment arms was low (33.8% in the combined seltorexant group, with 40.3% in the 5 mg group, 31.5% in the 10 mg group and 29.6% in the 20 mg group) and was lower than the rate observed in the placebo group (49.3%) and zolpidem group (42.5%). Most TEAEs were mild to moderate in intensity and resolved without sequelae.

Conference Call Information:

Minerva Neurosciences will hold a conference call and live audio webcast on June 24, 2019 at 8:30 a.m. Eastern Time to discuss the results of this trial. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 1644578. To access the webcast,

please go to https://engage.vevent.com/rt/minervaneurosciencesinc~062419.

The live webcast can also be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at ir.minervaneurosciences.com. The archived webcast will be available on the website beginning approximately two hours after the event for 90 days.

About Seltorexant (MIN-202)

Seltorexant is a selective orexin-2 receptor antagonist under co-development by Janssen Pharmaceutica N.V., a Pharmaceutical Company of Johnson & Johnson, and Minerva as adjunctive therapy for MDD and for the treatment of insomnia disorder. The orexin system in the brain is involved in the control of several key functions, including metabolism, stress response and wakefulness. This system promotes arousal (wakefulness) and is hypothesized to play a role in excessive arousal, which occurs in patients with insomnia and in subsets of patients with mood disorders, and to have clinical utility in the treatment of such patients.

About Insomnia

According to the American Academy of Sleep Medicine, approximately 30-35% of adults have brief symptoms of insomnia, 15-20% have short-term insomnia disorder (lasting less than three months), and 10% have chronic insomnia, which occurs at least three times per week for at least three months. Insomnia incurs a significant economic cost on society, with estimates of $63.2 billion in lost productivity.

Chronic insomnia can have a negative impact on health and can be a common comorbidity of many medical conditions, including diabetes, coronary heart disease, chronic obstructive pulmonary disease, arthritis, fibromyalgia and other chronic pain conditions. Individuals with insomnia disorder frequently have a comorbid mental disorder, including depressive and anxiety disorders.

Age and gender are clearly identified demographic risk factors for insomnia, with an increased prevalence in women and older adults. Insomnia is commonly seen in elderly populations and is associated with detrimental consequences for successful aging. Sleep disturbances among the elderly are associated with significant morbidity and mortality and increase the risk for nursing home placement. These findings are particularly relevant as the population of persons aged 65 years or older continues to grow.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat CNS diseases. Minerva's proprietary compounds include: roluperidone (MIN-101), in clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and Major Depressive Disorder (MDD); MIN-117, in clinical development for 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."

About the Minerva & Janssen collaboration

Minerva is developing seltorexant with Janssen Pharmaceutica N.V., a Pharmaceutical Company of Johnson & Johnson. Under the terms of the collaboration, Minerva has exclusive commercialization rights to seltorexant and other orexin molecules for the treatment of insomnia and all other indications including MDD in the Minerva Territory (EU, Iceland, Lichtenstein, Switzerland & Norway). Royalties on sales outside of the Minerva Territory are payable by Janssen. Minerva pays royalties on sales (excluding sales of products for the treatment of insomnia) within the Minerva Territory.

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 scope of current clinical trials and results of clinical trials with roluperidone, seltorexant, MIN-117 and MIN-301; the timing and scope of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these compounds; our ability to successfully develop and commercialize our therapeutic products; 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 roluperidone, seltorexant, MIN-117 and MIN-301 will advance further in the clinical trials process and whether and when, if at all, they 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 products will be successfully marketed if approved; 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; 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, 2019, filed with the Securities and Exchange Commission on May 6, 2019. 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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