

MINERVA NEUROSCIENCES, INC.

FORM 8-K (Current report filing)

Filed 05/31/17 for the Period Ending 05/30/17

Address	1601 TRAPELO ROAD SUITE 284 WALTHAM, MA 02451
Telephone	617-600-7373
CIK	0001598646
Symbol	NERV
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 30, 2017

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 284
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))

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 1.01 **Entry into a Material Definitive Agreement****Term Sheet with Johnson and Johnson**

On May 31, 2017, Minerva Neurosciences, Inc., a Delaware corporation (the “Company” or “Minerva”) announced that Minerva and Johnson & Johnson (“J&J”) entered into a binding term sheet on May 30, 2017 (the “Term Sheet”) to amend that certain Co-Development and License Agreement between Minerva and Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of J&J (“Janssen”), related to the Company’s MIN-202 product candidate. Minerva has also agreed to repurchase all Minerva stock held by J&J at a per share price of \$0.0001.

Amendment to Co-Development and License Agreement

Pursuant to the terms of the Term Sheet, Minerva and Janssen will enter into an amendment (the “Amendment”) to the Co-Development and License Agreement pursuant to which Minerva will gain global strategic control of the development of MIN-202 to treat insomnia, and Janssen will forego its right to royalties on MIN-202 insomnia sales in Minerva territories. Minerva will retain its current rights to MIN-202 as adjunctive therapy for major depressive disorder (MDD), which include an exclusive license in the European Union, Switzerland, Liechtenstein, Iceland and Norway, with royalties payable by Minerva to Janssen, and royalties on sales payable by Janssen to Minerva elsewhere worldwide.

Janssen has agreed, pursuant to the Term Sheet, to make an upfront payment to Minerva of \$30 million upon the effectiveness of the Amendment. Janssen has also agreed to make a \$20 million payment at the start of a Phase 3 insomnia trial for MIN-202, a \$20 million payment when 50% of the patients are enrolled in this trial, and further agreed to waive the remaining payments due from Minerva for Phase 2 development of MIN-202, which total approximately \$13 million.

Upon the effectiveness of the Amendment, Minerva will assume all financial responsibility for Phase 3 development costs for MIN-202 in insomnia. The effectiveness of the Amendment is contingent upon the closing of J&J’s pending acquisition of Actelion Ltd. and approval by the European Commission.

Stock Repurchase Agreement

In connection with the Amendment, Minerva has also agreed to enter into a stock repurchase agreement with Johnson & Johnson Innovation-JJDC Inc. to repurchase all of the approximately 3.9 million shares of Minerva stock held by Johnson & Johnson Innovation-JJDC Inc. at a per share price of \$0.0001, for an aggregate purchase price of approximately \$389 (the “Stock Repurchase Agreement”). The effectiveness of the Stock Repurchase Agreement is contingent upon the closing of J&J’s pending acquisition of Actelion Ltd. and approval by the European Commission.

The foregoing description of the Term Sheet does not purport to be complete and is qualified in its entirety by reference to the full text of the Term Sheet, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated by reference herein, as well as the full text of the contemplated Amendment and Stock Repurchase Agreement, which the Company intends to file with the Securities and Exchange Commission following their execution.

On May 31, 2017, the Company issued a press release relating to the Term Sheet described above, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01. **Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1	Binding Term Sheet dated May 30, 2017 by and between Minerva Neurosciences, Inc. and Johnson & Johnson
99.1	Press Release dated May 31, 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 31, 2017

INDEX OF EXHIBITS

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10.1	Binding Term Sheet dated May 30, 2017 by and between Minerva Neurosciences, Inc. and Johnson & Johnson
99.1	Press Release dated May 31, 2017

May 30, 2017

Strictly Confidential

Marc D. Beer
Chairman of the Board of Directors
Minerva Neurosciences, Inc.
1601 Trapelo Road, Suite 284
Waltham, MA 02451

Dear Marc,

In connection with Johnson & Johnson's ("J&J") pending acquisition of Actelion Ltd (the "Pending Acquisition"), J&J and Minerva Neurosciences, Inc. ("Minerva") have mutually agreed to the terms set forth in the binding term sheet attached hereto as Annex A and incorporated herein (the "Binding Term Sheet") with respect to J&J's ongoing relationship with Minerva.

This letter agreement and the Binding Term Sheet are intended to be a legally binding agreement between J&J and Minerva and set forth the material terms of the agreement between the parties with respect to the matters described therein. J&J and Minerva further agree to negotiate in good faith, and reach agreement on, definitive documentation to effect the agreement in the Binding Term Sheet as promptly as practicable following the date hereof. This letter agreement and the Binding Term Sheet may only be terminated in the event that J&J abandons the Pending Acquisition.

This letter agreement and the Binding Term Sheet shall be governed and construed in accordance with the laws of the State of New York without regard to principles of conflicts of laws.

This letter agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed and delivered by each of the parties hereto. Delivery of an executed counterpart by facsimile or other electronic image scan shall be as effective as delivery of a manually executed counterpart.

[remainder of page intentionally left blank]

If you are in agreement with the foregoing and the terms set forth in the Binding Term Sheet incorporated herein, please sign and return to J&J the enclosed copy of this letter agreement, and upon execution by J&J and Minerva, it shall become a binding agreement between us.

Very truly yours,

JOHNSON & JOHNSON,

by

/s/ Joaquin Duato

Name: Joaquin Duato

Title: Worldwide Chairman, Pharmaceuticals

Accepted and agreed as of the date first above written:

MINERVA NEUROSCIENCES, INC.,

by

/s/ Mark Levine

Name: Mark Levine

Title: General Counsel

Binding Term Sheet

This summary of terms (“Term Sheet”) sets forth the principal terms of the agreement between Johnson & Johnson (“J&J”) and Minerva Neurosciences, Inc. (“Minerva”) to address (and goes beyond addressing) concerns raised by the European Commission regarding J&J’s relationship with Minerva in connection with J&J’s pending acquisition of Actelion Ltd (the “Pending Acquisition”).

This Term Sheet is confidential and should be treated as such and should not be discussed with any other party, provided that J&J may provide a copy of this Term Sheet to the European Commission. Notwithstanding the foregoing, any disclosure which is required by stock exchange regulation or by applicable law as advised by the disclosing party’s counsel may be made without the prior consent of the other party, provided that the other party shall be given prompt notice of any such legally required written disclosure and the disclosing party, to the extent reasonably practicable, shall provide the other party an opportunity to comment on the proposed written disclosure prior to its disclosure or release.

The agreed upon terms are as follows:

- J&J grants Minerva the final say on all decisions related to the development of JNJ-7922 for the insomnia indication on a global basis. If J&J and Minerva disagree on whether any action in respect of quality, regulatory and medical safety issues that J&J is taking in the development of JNJ-7922 for the depression indication (or Minerva is taking in relation to the insomnia indication) could have an adverse impact on the development of JNJ-7922 for the insomnia indication (or on the depression indication, in the case of J&J), the matter will be referred to an independent third party expert (or panel of experts)
- J&J forgoes its right to 7% royalties on Minerva insomnia sales in Minerva territories
- J&J waives the remaining payments due from Minerva for Phase II development under the second stage cap (approximately \$13 million), which means J&J will fund 100% of the remaining Phase II development costs
- Minerva assumes financial responsibility for Phase III insomnia development costs
- Both parties will agree to forgo their right to opt out of further joint development of the program prior to Decision Point 4, except in the event of negative regulatory, clinical or safety signals
- All Minerva stock owned by J&J is canceled without consideration to J&J
- J&J agrees to make cash payments of up to \$70 million, as follows:
 - \$30 million upfront;
 - \$20 million at the start of a Phase III insomnia trial; and
 - \$20 million when 50% of the patients are enrolled in a Phase III insomnia trial

The transactions contemplated by any definitive documentation implementing the foregoing agreement (including the effectiveness of any amendments to the Co-Development and License Agreement, dated February 13, 2014, by and between Janssen Pharmaceutica, N.V. and Minerva) shall be conditioned on (1) the settlement of the Pending Acquisition and (2) the receipt by J&J of confirmation from the European Commission in writing that it either approves of or does not object to the terms of such definitive documentation.

Contact :

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

FOR IMMEDIATE RELEASE**MINERVA ANNOUNCES AMENDED AGREEMENT FOR MIN-202 IN INSOMNIA**

Minerva to gain global strategic control over development of MIN-202 for insomnia

Janssen cash payments to Minerva of up to \$70 million, including \$30 million upfront

All shares in Minerva held by an affiliate of Janssen (approximately 3.9 million shares representing approximately 10% of outstanding shares) to be repurchased at par value

Minerva Phase 2 development payments totaling \$13 million to be waived

Waltham, MA, May 31, 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 that it has entered into a binding term sheet to amend its co-development and license agreement with Janssen Pharmaceutica NV (Janssen) related to MIN-202 (JNJ 42827922), a selective orexin-2 receptor antagonist, and to repurchase all Minerva shares owned by Johnson & Johnson Innovation—JJDC, Inc. (an affiliate of Janssen). This amendment and the stock repurchase are conditional upon the closing of the pending acquisition of Actelion Ltd. by affiliates of Janssen and approval by the European Commission.

Under the amended agreement, Minerva will gain global strategic control of the development of MIN-202 to treat insomnia, and Janssen will forego its right to royalties on MIN-202 insomnia sales in Minerva territories. Minerva will retain its current rights to MIN-202 as adjunctive therapy for major depressive disorder (MDD), which include an exclusive license in the European Union, Switzerland, Liechtenstein, Iceland and Norway, with royalties payable by Minerva to Janssen, and royalties on sales payable by Janssen to Minerva elsewhere worldwide.

Payments to Minerva by Janssen under this new agreement include an upfront payment of \$30 million, \$20 million at the start of a Phase 3 insomnia trial for MIN-202 and \$20 million when 50% of the patients are enrolled in this trial. Janssen will waive the remaining payments due from Minerva for Phase 2 development of MIN-202, which total approximately \$13 million. Minerva will assume all financial responsibility for Phase 3 development costs for MIN-202 in insomnia. All Minerva stock currently owned by Johnson & Johnson Innovation—JJDC, Inc. totaling approximately 3.9 million shares and representing approximately 10% of total Minerva shares outstanding will be repurchased by Minerva at par value of \$.0001 per share or approximately \$389 in total.

“We view the new agreement with Janssen as a structure that will ensure a more focused and efficient clinical development of MIN-202 in insomnia by Minerva,” said Dr. Remy Luthringer, president and chief executive officer of Minerva. “We look forward to continuing our collaboration with Janssen while accelerating the clinical advancement of our portfolio. In addition, the infusion of financial resources under this agreement significantly extends Minerva’s financial runway.”

Minerva expects that these combined financial resources will support the development of MIN-101, its lead product candidate to treat negative symptoms in schizophrenia, and the development of MIN-202 in insomnia and MDD to the end of 2019. Within that time frame, Minerva expects to generate data readouts from its planned Phase 3 trial with MIN-101 and three Phase 2b trials with MIN-202 in both indications. Additional clinical activities planned during that period include a Phase 2 trial with MIN-117 and a Phase 1 trial with MIN-301.

About MIN-202 (JNJ 42827922)

MIN-202 is a selective orexin 2 receptor antagonist under development for the treatment of insomnia and as adjunctive therapy for MDD. In the brain, the orexin system is involved in the control of several key functions, including metabolism and wakefulness. MIN-202 seeks to inhibit the activity of the neurons that promote wakefulness by selectively blocking the orexin 2 receptor. Rather than making an individual sleepier, blocking the orexin 2 receptor reduces the level of the neurotransmitters that signal the brain to maintain vigilance and wakefulness.

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 approval by the European Commission and subsequent closing of the pending acquisition of Actelion Ltd. by affiliates of Janssen; our ability to negotiate and execute the definitive agreements described above; the timing and results of future clinical milestones with MIN-202 in insomnia and major depressive disorder, including the timing and scope of future clinical trials and results of clinical trials with this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our agreements with Janssen related to MIN-202; our ability to successfully develop and commercialize MIN-101, MIN-202, MIN-117 and MIN-301; 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, the inherent uncertainty in approval by the European Commission and subsequent closing of the pending acquisition of Actelion Ltd. by affiliates of Janssen; whether MIN-101, MIN-202, MIN-117 and MIN-301 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, MIN-202, MIN-117 and MIN-301, if any, will be consistent with the

results of past clinical trials; whether MIN-101, MIN-202, MIN-117 and MIN-301 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.