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): March 9, 2020

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**	**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))

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 March 9, 2020, Minerva Neurosciences, Inc. (the "Company") issued a press release reporting its 2019 fourth quarter and year ended financial results as well as an update on timing of expected top-line results from the Company's Phase 3 clinical trial of roluperidone. 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 March 9, 2020.

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: March 9, 2020

Exhibit 99.1

Contact:

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

FOR IMMEDIATE RELEASE

MINERVA NEUROSCIENCES REPORTS FISCAL 2019 FOURTH QUARTER AND YEAR END FINANCIAL RESULTS AND BUSINESS UPDATES

Company confirms timing of expected top-line results from Phase 3 roluperidone trial in Q2 2020

Management to host conference call today at 8:30 a.m. Eastern Time

Waltham, MA, March 9, 2019 – Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat unmet medical needs of central nervous system (CNS) disorders, today reported key business updates and financial results for the fourth quarter and fiscal year ended December 31, 2019.

Clinical Program Updates

Roluperidone

The Company is pleased to confirm its previous guidance that top-line results from the Phase 3 trial with roluperidone are expected in the second quarter of 2020. As announced in February, enrollment of 515 patients has been achieved in the 12-week core phase of a pivotal trial for the treatment of negative symptoms, the leading unmet medical need in schizophrenia.

This trial is a multicenter, randomized, double-blind, parallel-group, placebo-controlled, 12-week trial to evaluate the efficacy and safety of 32 milligram (mg) and 64 mg doses of roluperidone as measured by the Positive and Negative Syndrome Scale. The primary endpoint is the Marder negative symptoms factor score. The core 12-week study, which the Company expects to read out in the second quarter, will be followed by an optional 40-week, open-label extension period during which patients on the drug continue receiving their original dose and patients on placebo receive one of the two doses of roluperidone.

Seltorexant

The Company announced positive data readouts in 3 Phase 2b studies and one Phase 1b trial with seltorexant (MIN-202) during 2019. Three of these trials were in major depressive disorder (MDD) and one was in insomnia disorder.

The Company is currently in discussions with its partner, Janssen Pharmaceutica NV, regarding the Phase 3 strategic development program for seltorexant, with a target indication of adjunctive treatment of MDD (aMDD) in patients with insomnia symptoms. The Company and Janssen are also currently consulting with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency about this target indication and these trials, and they have recently attended the end-of-Phase 2 meeting with FDA to discuss the design of Phase 3 studies.

MIN-301

The Company is developing MIN-301, a pre-clinical candidate for the potential treatment of Parkinson's disease and other neurodegenerative disorders. Building upon positive data in non-primate pre-clinical models, the Company is continuing to conduct pre-clinical studies in preparation for regulatory filings leading toward entry into humans.

"We are on track to read out top-line results of the roluperidone Phase 3 study in the second quarter of 2020," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva, "and we continue to expand our understanding of this exciting agent as a treatment for negative symptoms in schizophrenia and beyond. In parallel, we are in discussions with Janssen about moving forward into Phase 3 with seltorexant in 2020."

Fourth Quarter and Year Ended 2019 Financial Results

- **Net (Loss) Income:** Net loss was $29.9 million for the fourth quarter of 2019, or loss per share of $0.77 (basic and diluted), compared to net loss of $13.2 million for the fourth quarter of 2018, or loss per share of $0.34 (basic and diluted). Net loss was $72.2 million for the year ended December 31, 2019, or loss per share of $1.85 (basic and diluted), compared to a net loss of $50.2 million, or loss per share of $1.29 (basic and diluted) for the year ended December 31, 2018.
- **R&D Expenses:** Research and development (R&D) expenses were $28.5 million in the fourth quarter of 2019, compared to $9.0 million in the fourth quarter of 2018. R&D expenses were $58.1 million for the year ended December 31, 2019, compared to $34.9 million for the year ended December 31, 2018. The increase in R&D expenses during the fourth quarter and year ended December 31, 2019 primarily reflects a $19.0 million non-cash impairment expense for the discontinued development of MIN-117 and higher development expenses for the Phase 3 clinical trial of roluperidone and the Phase 2b clinical trial of MIN-117.
- **G&A Expenses:** General and administrative (G&A) expenses were $3.8 million in the fourth quarter of 2019, compared to $4.6 million in the fourth quarter of 2018. G&A expenses were $17.7 million for the year ended December 31, 2019, compared to $16.8 million for the year ended December 31, 2018. This increase in G&A expenses during the fourth quarter and year ended December 31, 2019 was primarily due to an increase in non-cash stock-based compensation expenses and higher professional fees to support pre-commercial activities.
- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities as of December 31, 2019 were approximately $46.0 million, compared to $88.1 million as of December 31, 2018.

Conference Call Information:

Minerva Neurosciences will host a conference call and live audio webcast today at 8:30 a.m. Eastern Time to discuss these results and recent business activities. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 7176196.

The live webcast can 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 Minerva Neurosciences

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 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 scope of future clinical trials and results of clinical trials with roluperidone (MIN-101), seltorexant (MIN-202) and MIN-301; the clinical and therapeutic potential of these compounds; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; 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 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 Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 9, 2020. 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.

CONDENSED CONSOLIDATED BALANCE SHEET DATA
(Unaudited)

	December 31, 2019	December 31, 2018
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 21,413	$ 50,235
Marketable securities	24,442	37,763
Restricted cash	100	100
Prepaid expenses and other current assets	1,182	1,921
Total current assets	47,137	90,019
Equipment, net	16	33
Other noncurrent assets	15	15
Operating lease right-of-use assets	262	—
In-process research and development	15,200	34,200
Goodwill	14,869	14,869
Total Assets	$ 77,499	$ 139,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,317	$ 1,799
Accrued expenses and other current liabilities	4,139	1,810
Operating leases	173	—
Total current liabilities	6,629	3,609
Long-Term Liabilities:		
Deferred taxes	1,803	4,057
Deferred revenue	41,176	41,176
Other noncurrent liabilities	—	29
Noncurrent operating leases	111	—
Total liabilities	49,719	48,871
Stockholders' Equity:		
Common stock	4	4
Additional paid-in capital	314,512	304,814
Accumulated deficit	(286,736)	(214,553)
Total stockholders' equity	27,780	90,265
Total Liabilities and Stockholders' Equity	$ 77,499	$ 139,136

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31, (in thousands, except per share amounts)		Twelve Months Ended December 31 (in thousands, except per share amounts)	
	2019	2018	2019	2018
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	28,524	9,008	58,123	34,889
General and administrative	3,843	4,620	17,741	16,841
Total operating expenses	32,367	13,628	75,864	51,730
Foreign exchange losses	(11)	(5)	(29)	(5)
Investment income	206	430	1,456	1,674
Interest expense	—	—	—	(110)
Loss before income taxes	(32,172)	(13,203)	(74,437)	(50,171)
Benefit for income taxes	(2,254)	—	(2,254)	—
Net (loss) income	$ (29,918)	$ (13,203)	$ (72,183)	$ (50,171)
Loss per share:				
Basic and diluted	$ (0.77)	$ (0.34)	$ (1.85)	$ (1.29)
Weighted average shares:				
Basic and diluted	39,037	38,888	39,014	38,793