Vanda Pharmaceuticals Inc. Form 8-K February 13, 2019

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): February 13, 2019

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-34186 (Commission 03-0491827 (IRS Employer Edgar Filing: Vanda Pharmaceuticals Inc. - Form 8-K

File No.)

Identification No.)

2200 Pennsylvania Avenue NW

Suite 300E

Washington, DC 20037

(Address of principal executive offices and zip code)

Registrant s telephone number, including area code: (202) 734-3400

Not Applicable (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 2.02. Results of Operations and Financial Condition.

On February 13, 2019, Vanda Pharmaceuticals Inc. (Vanda) issued a press release and is holding a conference call regarding its results of operations and financial condition for the quarter and year ended December 31, 2018. The full text of the press release which includes information regarding Vanda s use of Non-GAAP financial measures, is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are forward-looking statements under the securities laws, including, but not limited to, Vanda s financial guidance for 2019. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, or the neg similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Important factors that could cause actual results to differ materially from those reflected in Vanda s forward-looking statements include, among others: Vanda s assumptions regarding its ability to continue to grow its business in the U.S., Vanda s ability to complete the clinical development and obtain regulatory approval of tradipitant for the treatment of gastroparesis and/or the treatment of chronic pruritus in atopic dermatitis, the outcome of the lawsuit initiated by Vanda against the FDA relating to tradipitant, the ability of HETLIOZ® to provide significant benefit in the treatment of the symptoms of jet lag disorder, Vanda s ability to obtain marketing approval for the use of HETLIOZ® in the treatment of jet lag disorder, Vanda s ability to complete the clinical development and obtain regulatory approval of tasimelteon for the treatment of sleep disorders in patients with SMS and other factors that are described in the Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations sections of Vanda s annual report on Form 10-K for the fiscal year ended December 31, 2017 and guarterly report on Form 10-Q for the quarter ended September 30, 2018, which are on file with the SEC and available on the SEC s website at www.sec.gov. Additional factors may be set forth in those sections of Vanda s annual report on Form 10-K for the year ended December 31, 2018, to be filed with the SEC in the first guarter of 2019. In addition to the risks described above and in Vanda s annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Vanda s results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information conveyed on the conference call will be provided only as of the date of the call, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the call after the date thereof, whether as a result of new information, future events or otherwise.

The information in Item 2.02 of this current report on Form 8-K and the Exhibit attached hereto shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit	
No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated February 13, 2019.

SIGNATURES

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.

Dated: February 13, 2019

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams Name: Timothy Williams Title: Senior Vice President, General Counsel and

Secretary