

Vanda Pharmaceuticals Inc.
Form 8-K
November 02, 2016

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): November 2, 2016

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-34186
(Commission

File No.)

03-0491827
(IRS Employer

Identification No.)

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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))

Item 2.02. Results of Operations and Financial Condition.

On November 2, 2016, 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 ended September 30, 2016. 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 2016. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, or the negative of 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 ability to successfully commercialize HETLIOZ[®] for the treatment of Non-24 in the U.S. and Europe; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ[®]; Vanda s ability to generate U.S. sales of Fanapt[®] for the treatment of schizophrenia; the timing and costs of Vanda s establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt[®] in the U.S.; Vanda s dependence on third-party manufacturers to manufacture HETLIOZ[®] and Fanapt[®] in sufficient quantities and quality; Vanda s limited sales and marketing infrastructure; the regulatory status of Fanapt[®] in Europe; Vanda s ability to successfully commercialize HETLIOZ[®] and Fanapt[®] outside the U.S.; Vanda s ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights; Vanda s ability to obtain the capital necessary to fund its research and development or commercial activities; a loss of rights to develop and commercialize Vanda s products under its license agreements; the ability to obtain and maintain regulatory approval of Vanda s products, and the labeling for any approved products; the timing and success of preclinical studies and clinical trials conducted by Vanda or its development partners; a failure of Vanda s products to be demonstrably safe and effective; the size and growth of the potential markets for Vanda s products and the ability to serve those markets; Vanda s expectations regarding trends with respect to its revenues, costs, expenses and liabilities; the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the FDA s approval of Fanapt[®]; the scope, progress, expansion, and costs of developing and commercializing Vanda s products; Vanda s failure to identify or obtain rights to new products; a loss of any of Vanda s key scientists or management personnel; limitations on Vanda s ability to utilize some or all of its prior net operating losses and orphan drug and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; use of existing cash, cash equivalents and marketable securities 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, 2015 and quarterly report on Form 10-Q for the quarter ended June 30, 2016, which are on file with the SEC and available on the SEC s website at www.sec.gov. Additional factors may be described in those sections of Vanda s quarterly report on Form 10-Q for the quarter ended September 30, 2016, to be filed with the SEC in the fourth quarter of 2016. 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.

(d) Exhibits

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press release of Vanda Pharmaceuticals Inc. dated November 2, 2016. |

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.

VANDA PHARMACEUTICALS INC.

Dated: November 2, 2016

By: /s/ Richard L. Gulino

Name: Richard L. Gulino

Title: Senior Vice President, General Counsel