

Vanda Pharmaceuticals Inc.
Form 8-K
May 08, 2014

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 8, 2014

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 May 8, 2014, Vanda Pharmaceuticals Inc. (the Company or Vanda) issued a press release and is holding a conference call regarding its results of operations and financial condition for the quarter ended March 31, 2014. The press release 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, the Company's financial guidance for 2014. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, terms and 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 the Company's forward-looking statements include, among others: Vanda's ability to successfully commercialize HETLIOZ (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S.; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ ; Vanda's dependence on third-party manufacturers to manufacture HETLIOZ in sufficient quantities and quality; Vanda's limited sales and marketing infrastructure; the regulatory status of tasimelteon in Europe; Vanda's ability to obtain the capital necessary to fund its research and development or commercial activities; Vanda's loss of rights to develop and commercialize its products under its license and sublicense agreements; the failure to obtain, or any delay in obtaining, regulatory approval for Vanda's products, particularly HETLIOZ outside the U.S., or to comply with ongoing regulatory requirements; the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda's inability to successfully commercialize Fanapt® outside of the U.S. and Canada; a failure of Vanda's products to be demonstrably safe and effective; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; 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 potential litigation; losses incurred from product liability claims made against Vanda 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, 2013 which is on file with the SEC and available on the SEC's website at www.sec.gov. 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 May 8, 2014. |

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.

By: /s/ James P. Kelly
Name: James P. Kelly
Title: Senior Vice President, Chief Financial
Officer, Secretary, and Treasurer

Dated: May 8, 2014