

Vanda Pharmaceuticals Inc.
Form 8-K
November 07, 2012

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 7, 2012

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

001-34186

03-0491827

Edgar Filing: Vanda Pharmaceuticals Inc. - Form 8-K

(State or other jurisdiction
of incorporation)

(Commission
File No.)

(IRS Employer
Identification No.)

2200 Pennsylvania Avenue N.W.

Suite 300E

Washington, D.C. 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 7, 2012, 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 September 30, 2012. 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. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, or the 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: the inability to reach agreement with the FDA regarding Vanda's regulatory approval strategy or proposed path to approval for tasimelteon; the failure of Vanda's clinical trials to demonstrate the safety and/or efficacy of tasimelteon in the treatment of Non-24-Hour Disorder or Major Depressive Disorder; Vanda's failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda's ability to successfully commercialize Fanapt® outside of the U.S. and Canada; delays in the completion of Vanda's and its partners' clinical trials; a failure of Vanda's products, product candidates or partnered products to be demonstrably safe and effective; a lack of acceptance of Vanda's products, product candidates or partnered products in the marketplace, or a failure to become or remain profitable; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; Vanda's inability to obtain the capital necessary to fund additional research and development activities; Vanda's failure to identify or obtain rights to new products or product candidates; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda's ability to utilize some or all of its prior net operating losses and research and development credits; a loss of any of Vanda's key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda's products or product candidates under its license and sublicense agreements 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, 2011 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, 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 7, 2012. |

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 Kelly
Name: James Kelly
Title: Chief Financial Officer

Dated: November 7, 2012