

Vanda Pharmaceuticals Inc.
Form 8-K
October 24, 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): October 24, 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.)

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

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 1.01. Entry into a Material Definitive Agreement.

On October 24, 2016, Vanda Pharmaceuticals Inc. (Vanda) announced that it has entered into a License Agreement (the License Agreement) with Taro Pharmaceuticals USA, Inc. (Taro USA) and Taro Pharmaceutical Industries Ltd. (Taro Israel) and together with Taro USA and their respective affiliates, Taro) settling Vanda s patent infringement litigation against Taro (the Litigation) in the U.S. District Court for the District of Delaware (the Court). In the Litigation, Vanda alleges that Taro s Abbreviated New Drug Application (ANDA) seeking approval to market generic versions of Fanapt® (iloperidone) in the U.S. infringes certain U.S. patents owned by Vanda that cover Fanapt®.

In accordance with legal requirements, Vanda and Taro have agreed to submit the License Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. Vanda and Taro have also agreed to file stipulations of dismissal with the Court regarding the Litigation. The License Agreement provides for a full settlement of the claims that were asserted in the Litigation, and includes a release by Vanda of all iloperidone-related infringement claims against Taro based on conduct prior to the effective date of the License Agreement. The License Agreement also provides for the joint submission to the Court, for its approval, of a consent judgment enjoining Taro from making, using, selling, offering for sale, or importing into the U.S., the iloperidone products that are the subject of Taro s ANDA except pursuant to a license from Vanda, and enjoining Taro from inducing or contributing to such infringement by others except pursuant to such a license from Vanda.

Under the License Agreement, Vanda granted Taro a non-exclusive license to manufacture and commercialize in the U.S. Taro s generic versions of the Fanapt® Products (as defined in the License Agreement) after the Trigger Date (as defined below).

Under the License Agreement, the Trigger Date is November 2, 2027, unless prior to that date Vanda obtains pediatric exclusivity, in which case the Trigger Date will be May 2, 2028; however, Taro may be able to enter the market earlier under certain circumstances. Such circumstances relate to the resolution of any other third party Fanapt® patent litigation and the entry of certain other third party generic versions of Fanapt®, among other events.

Vanda also agreed that if it enters into any similar agreements with other parties with respect to generic versions of Fanapt® that allow such other parties the right to sell generic versions of Fanapt® earlier than the date on which Taro is first permitted to sell its generic version of Fanapt® under the License Agreement, then Taro will receive the benefit of such earlier date.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreement, which will be filed with the U.S. Securities and Exchange Commission (the SEC) as an exhibit to Vanda s Annual Report on Form 10-K for the fiscal year ending December 31, 2016.

The press release announcing the entry into the License Agreement and the settlement of the Litigation is furnished as Exhibit 99.1 to this current report on Form 8-K.

Forward-Looking Statements

This report and the press release furnished hereto as Exhibit 99.1 contain forward-looking statements, including statements regarding the anticipated results and actions to be taken under the License Agreement, plans to submit the License Agreement for regulatory approval and the potential dismissal of the Litigation. These forward-looking statements are based on management s expectations and assumptions as of the date of this report and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to risks regarding whether regulatory authorities challenge the enforceability of or seek to enjoin the entry into the License Agreement, whether the Court will grant orders dismissing the Litigation, whether additional third parties may seek to market generic versions of Fanapt® and the results of any litigation that Vanda

files to defend and/or assert its patents against such third parties, 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 in this report and the press release is provided only as of the date hereof, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements contained herein after the date hereof, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
--------------------	--------------------

99.1	Press Release of Vanda Pharmaceuticals Inc., dated October 24, 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: October 24, 2016

By: /s/ Richard L. Gulino

Name: Richard L. Gulino

Title: Senior Vice President, General Counsel