

Vanda Pharmaceuticals Inc.
Form 8-K
December 22, 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): December 22, 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 1.01. Entry into a Material Definitive Agreement.

On December 22, 2014, Vanda Pharmaceuticals Inc. (Vanda), issued a press release announcing that it has entered into a settlement agreement (the Settlement Agreement) with Novartis Pharma AG and certain of its affiliates (collectively, Novartis) and will dismiss the arbitration proceedings initiated in May 2014 related to the license of Fanapt® (the Arbitration). The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Settlement Agreement

Pursuant to the terms of the Settlement Agreement, Vanda and Novartis have agreed to dismiss the ongoing Fanapt® Arbitration and to release each other from any related claims. Also under the Settlement Agreement, Novartis will (i) transfer all US and Canadian rights in the Fanapt® franchise to Vanda, (ii) make a \$25 million equity investment in Vanda at a price per share equal to \$13.82, and (iii) grant to Vanda an exclusive worldwide license to AQW051, a phase II alpha-7 nicotinic acetylcholine receptor partial agonist. The Settlement Agreement is subject to the closing of the various transactions contemplated therein with an expected effective date of December 31, 2014 (the Effective Date).

Other Agreements

Vanda and Novartis have entered into an asset transfer agreement relating to the transfer of the US and Canadian rights in the Fanapt® franchise to Vanda (the Fanapt® Asset Transfer Agreement). Pursuant to the Fanapt® Asset Transfer Agreement, Vanda will receive all existing Fanapt® inventory and the rights in and to Fanapt® that were licensed to Novartis by Vanda pursuant to the parties Amended and Restated Sublicense Agreement dated as of October 12, 2009 (the Existing License Agreement). Upon the closing of the Fanapt® Asset Transfer Agreement, which is subject to customary closing conditions, the Existing License Agreement will terminate. The parties have also entered into several additional agreements (the Ancillary Agreements) to further enable the orderly transfers of certain assets and liabilities, including but not limited to, all Fanapt® inventory.

In addition, Novartis will assign to Vanda all of its rights under that certain Sublicense Agreement, dated as of November 20, 1997, by and between Novartis and Titan Pharmaceuticals (Titan) relating to Fanapt® (the Titan Sublicense Agreement). Vanda will have the right to commercialize Fanapt® worldwide without any royalty or milestone obligations to Novartis. Pursuant to the Titan Sublicense Agreement, Vanda will have a tiered royalty obligation to Titan and Sanofi (Sanofi) at a percentage rate in the mid-twenties on Fanapt® net sales in the US until November 2016, the expiry of the US new chemical entity (NCE) patent. After the expiration of the NCE patent in the Major Markets (US, United Kingdom, Germany, France, Italy, Spain and Japan) and some non-major markets, Vanda will have a fixed royalty obligation to Sanofi on Fanapt® net sales of up to nine percent (9%). Under the Titan Sublicense Agreement, Vanda will be required to use its commercially reasonable efforts to commercialize Fanapt®. Either Vanda or Titan may terminate the Titan Sublicense Agreement under certain circumstances, including a material breach of the agreement by the other. In the event that Vanda terminates the Titan Sublicense Agreement, or if Titan terminates due to Vanda's breach, all rights licensed and developed by Vanda under the Titan Sublicense Agreement will revert or otherwise be licensed back to Titan on an exclusive basis.

Novartis will also assign to Vanda all of its rights under that certain Toll Manufacturing and Supply Agreement, dated as of May 1, 2006, by and between Novartis and Patheon Inc. (Patheon), as amended (the Fanapt® Patheon Supply Agreement) solely as it relates to Fanapt®. Under the Fanapt® Patheon Supply Agreement, Vanda may procure bulk, partially packaged and finished supplies of various dosages of Fanapt® for sale worldwide. Vanda will be responsible for sourcing the supply of the active pharmaceutical ingredient (iloperidone), and Patheon will manufacture 1, 2, 4, 6, 8, 10 and 12 mg tablets pursuant to orders placed by Vanda. The Fanapt® Patheon Agreement contains specific forecasting, order lead time, minimum order quantities, yield requirements, delivery terms and alternative manufacturing provisions. Generally, all product shipped to Vanda must have a remaining shelf life of

more than four-fifths of its total shelf life, but no less than one (1) year of shelf life remaining for certain products. Following the closing of the transactions described above, the Fanapt® Patheon Supply Agreement continues on a year-to-year basis, and can be terminated by either party on at least twelve (12) months prior notice, or prior to the end of the then current term for uncured breach, insolvency/bankruptcy, or by Vanda if a regulatory action prevents the supply of iloperidone to Patheon or otherwise the purchase or sale of Fanapt®.

Vanda and Novartis have also entered into a stock purchase agreement (the *Stock Purchase Agreement*) under which Novartis will purchase 1,808,973 shares of Vanda's Common Stock (the *Shares*), at a purchase price equal to \$13.82 per Share, which represents a ten percent (10%) premium over the average closing price during the ten (10) trading days preceding the signing of the Stock Purchase Agreement, for an aggregate purchase of \$25,000,000. The Shares will be sold to Novartis pursuant to Vanda's effective shelf registration statement on Form S-3 and an accompanying prospectus (Registration Statement No. 333-191434) filed with the Securities and Exchange Commission (the *SEC*) on September 27, 2013 and declared effective by the SEC on October 4, 2013 and a final prospectus supplement to be filed with the SEC in connection with Vanda's sale of the Shares to Novartis. The Shares will be subject to an initial lock-up period beginning on the closing date of the Stock Purchase Agreement and ending on January 27, 2015, during which Novartis will be prohibited from selling any Shares. Following the initial lock-up period, Novartis may sell Shares, subject to maximum daily volume limitations. Novartis has also agreed to certain customary standstill provisions relating to Vanda and its stock.

Vanda has also entered into a license agreement with Novartis pursuant to which Vanda will receive an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize AQW051, a phase II alpha-7 nicotinic acetylcholine receptor partial agonist, for all human indications (the *AQW051 License Agreement*). The patent describing AQW051 as a new chemical entity expires in September 2023 in the US and Major Markets, absent any applicable patent term adjustments. Under the AQW051 License Agreement, Vanda will be obligated to use its commercially reasonable efforts to develop and commercialize AQW051 and will be responsible for all development costs under the AQW051 License Agreement. Novartis will be eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens. Either party may terminate the AQW051 License Agreement under certain circumstances, including a material breach of the agreement by the other. In the event that Vanda terminates the AQW051 License Agreement, or if Novartis terminates due to Vanda's breach, all rights licensed and developed by Vanda under the AQW051 License Agreement will revert or otherwise be licensed back to Novartis on an exclusive basis.

The closing of the transactions contemplated by the Fanapt® Asset Transfer Agreement, the Stock Purchase Agreement, the AQW051 License Agreement and the Ancillary Agreements is subject to customary closing conditions, but it is the current intention of Vanda and Novartis that such closing will occur on or about the Effective Date. Vanda expects to stop receiving royalties on Novartis sales of Fanapt® as of the Effective Date, at which point, except as otherwise provided for in the Ancillary Agreements, Vanda shall record Fanapt® revenue on US sales and be responsible for the costs associated with the further commercialization of Fanapt®.

Copies of the Settlement Agreement, the Fanapt® Asset Transfer Agreement, the Titan Sublicense Agreement, the Fanapt® Patheon Supply Agreement, the Stock Purchase Agreement and the AQW051 License Agreement will be filed as exhibits to Vanda's annual report on Form 10-K for the fiscal year ending December 31, 2014. The foregoing description of the terms of such agreements is qualified in its entirety by reference to the full text of such exhibits.

Item 1.02. Termination of a Material Definitive Agreement.

The information in Item 1.01 above is incorporated by reference into this Item 1.02 with respect to the termination of the Existing License Agreement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Vanda Pharmaceuticals Inc., dated December 22, 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: December 22, 2014