

Vanda Pharmaceuticals Inc.
Form 8-K
August 25, 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): August 25, 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 8.01. Other Events.

As previously disclosed, in June 2014 Vanda Pharmaceuticals Inc. (the Company) filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (the Delaware District Court). The suit sought an adjudication that Roxane has infringed one or more claims of the Company's U.S. Patent No. 8,586,610 (the 610 Patent) by submitting to the FDA an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the 610 Patent in November 2027. In addition, pursuant to the settlement agreement with Novartis Pharma AG (Novartis), the Company assumed Novartis' patent infringement action against Roxane in the Delaware District Court. That suit alleged that Roxane has infringed one or more claims of U.S. Patent RE39198 (the 198 Patent), which is licensed exclusively to the Company, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the 198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded on March 4, 2016.

On August 25, 2016, the Delaware District Court ruled in favor of the Company, finding that Roxane's proposed products infringed the asserted claims of the 610 Patent and the 198 Patent. The Delaware District Court ruled that the Company is entitled to a permanent injunction against Roxane enjoining Roxane from infringing the 610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the 610 Patent ANDA until the expiration of the 610 Patent in November 2027.

A press release announcing the Delaware District Court's decision is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Description

99.1 Press release of Vanda Pharmaceuticals Inc. dated August 25, 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: August 25, 2016

By: /s/ Richard S. Gulino

Name: Richard S. Gulino

Title: Senior Vice President, General Counsel