

Vanda Pharmaceuticals Inc.
Form 8-K
December 19, 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): December 15, 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 2015 Vanda Pharmaceuticals Inc. (the Company) filed separate patent infringement lawsuits in the United States District Court for the District of Delaware against Roxane Laboratories, Inc. (Roxane), Inventia Healthcare Pvt. Ltd. (Inventia), and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin) (collectively, the Defendants) seeking an adjudication that the respective Defendants infringed one or more claims of the Company's U.S. Patent No. 9,138,432 (the 432 Patent) and/or the Company's U.S. Patent No. 8,586,610 (the 610 Patent) by submitting to the U.S. Food and Drug Administration an Abbreviated New Drug Application for a generic version of Fanapt® prior to the expiration of the 432 Patent in September 2025 or the 610 Patent in November 2027, as applicable. A trial on these matters was scheduled to begin on May 15, 2017.

On December 15, 2016, following a submission by the parties suggesting that it may be appropriate to remove the May 15, 2017 trial from the District Court's calendar pending the Federal Circuit decision in Roxane's appeal of the District Court's August 25, 2016 ruling finding that Roxane's proposed products infringed the asserted claims of the 610 Patent (as previously disclosed), the District Court removed the May 15, 2017 trial from the calendar and adopted a new schedule for discovery. Additionally, within fourteen days after any decision on the merits in the Roxane appeal, the parties will submit to the District Court a status report and request a schedule for trial. Vanda and Inventia have entered into a confidential stipulation regarding any potential launch date of Inventia's generic ANDA product. Vanda and Lupin have also entered into a confidential stipulation regarding any potential launch date of Lupin's ANDA Product.

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: December 19, 2016

By: /s/ Richard L. Gulino

Name: Richard L. Gulino

Title: Senior Vice President, General Counsel