

Vanda Pharmaceuticals Inc.
Form 8-K
August 14, 2018

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 14, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

As previously disclosed, in August 2016, the U.S. District Court for the District of Delaware (the Delaware District Court) ruled that Vanda Pharmaceuticals Inc. (the Company) was entitled to a permanent injunction against Roxane enjoining Roxane from infringing the Company s U.S. Patent No. 8,586,610 (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 Abbreviated New Drug Application (ANDA) until the expiration of the 610 Patent in November 2027. In September 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals (the Federal Circuit). In July 2017, Roxane Laboratories, Inc. (Roxane), now a subsidiary of Hikma Pharmaceuticals PLC (Hikma), petitioned the Federal Circuit to substitute Roxane with new defendants West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (each of which is a subsidiary of Hikma and both of which are referred to collectively herein as West-Ward). In April 2018, the Federal Circuit affirmed the Delaware District Court s decision that West-Ward infringed the 610 Patent. In June 2018, West-Ward filed with the Federal Circuit a petition seeking rehearing *en banc* and the Company s response was filed in July 2018.

On August 14, 2018, the Circuit Court denied West-Ward s petition seeking panel rehearing and rehearing *en banc*.

A press release announcing the Circuit 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 | <u>Press release of Vanda Pharmaceuticals Inc. dated August 14, 2018.</u> |

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.

Dated: August 14, 2018

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel and Secretary