

**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): January 13, 2020**

**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.)

**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 (see General Instruction A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	VNDA	The Nasdaq Global Market

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, Vanda Pharmaceuticals Inc. (“Vanda”) has been involved in litigation with Roxane Laboratories, Inc. (“Roxane”) and its affiliates, West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp (together, “West-Ward”), since Vanda filed a lawsuit against Roxane in the U.S. District Court for the District of Delaware (the “Delaware District Court”) for patent infringement in June 2014. The lawsuit was filed in response to Roxane’s submission to the U.S. Food and Drug Administration (the “FDA”) of an Abbreviated New Drug Application (“ANDA”) for a generic version of Fanapt® prior to the expiration of certain of Vanda’s patents covering Fanapt®, including U.S. Patent No. 8,586,610 (the “‘610 Patent”). In August 2016, the Delaware District Court ruled in Vanda’s favor, permanently enjoining Roxane from manufacturing, using, selling, offering to sell, distributing or importing any generic iloperidone product described in Roxane’s ANDA until the expiration of the ‘610 Patent in November 2027, or May 2028 if Vanda obtains pediatric exclusivity. In April 2018, following an appeal by Roxane of the Delaware District Court’s decision to the Federal Circuit Court of Appeals (the “Federal Circuit”), the Federal Circuit affirmed the Delaware District Court’s ruling. In June 2018, West-Ward, having replaced Roxane as defendants following the acquisition of Roxane by West-Ward’s parent company, Hikma Pharmaceuticals PLC, petitioned the Federal Circuit for a rehearing en banc. In August 2018, the Federal Circuit denied West-Ward’s petition. In January 2019, West-Ward filed a petition in the U.S. Supreme Court for a writ of certiorari seeking reversal of the Federal Circuit’s decision. In March 2019, the U.S. Supreme Court invited the Solicitor General of the U.S. to file a brief in the matter expressing the views of the U.S., and on January 13, 2020, the U.S. Supreme Court denied West-Ward’s petition.

A press release announcing the U.S. Supreme Court’s decision is attached hereto as Exhibit 99.1 and incorporated by reference herein.

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**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release of Vanda Pharmaceuticals Inc. dated January 13, 2020.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**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: January 13, 2020

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel  
and Secretary



### **Vanda Pharmaceuticals Wins Key U.S. Supreme Court Patent Ruling on Fanapt®**

**WASHINGTON** – January 13, 2020 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) announced today that the U.S. Supreme Court has denied the petition for a writ of certiorari filed by West-Ward Pharmaceuticals (West-Ward), a subsidiary of Hikma Pharmaceuticals, relating to Vanda’s U.S. Patent number 8,586,610 (the ‘610 Patent) for Fanapt®. This order by the U.S. Supreme Court ensures that the ‘610 patent will remain exclusive at least through November 2, 2027, absent further challenges from other parties.

By denying the petition for a writ of certiorari, the Supreme Court leaves undisturbed the U.S. Court of Appeals for the Federal Circuit decision that West-Ward’s Abbreviated New Drug Application for iloperidone infringed the ‘610 Patent, and that West-Ward had not proven the ‘610 Patent invalid.

“We are pleased the U.S. Supreme Court denied certiorari and that the Federal Circuit’s decision stands,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO. “Upholding our Fanapt® invention validates our approach to innovation, and enables us to continue investing in important, life-changing discoveries.”

#### **About Vanda Pharmaceuticals Inc.**

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit [www.vandapharma.com](http://www.vandapharma.com)

#### **About Fanapt®**

For full U.S. Prescribing Information for Fanapt®, including indication, Boxed Warnings and Important Safety Information, visit our Web site at [www.fanapt.com](http://www.fanapt.com).

## CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release, including, but not limited to, the statement concerning the duration of patent exclusivity for the '610 Patent, are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, Vanda's assumptions regarding the duration of exclusivity for the '610 Patent and the likelihood of additional challenges 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, 2018 and quarterly report on Form 10-Q for the quarter ended September 30, 2019, which are on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional factors may be described in those sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2019, to be filed with the SEC in the first quarter of 2020. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, 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 release is provided only as of the date of this release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

### **Corporate Contact:**

AJ Jones II  
Chief Corporate Affairs and Communications Officer  
Vanda Pharmaceuticals Inc.  
202-734-3400  
[pr@vandapharma.com](mailto:pr@vandapharma.com)

Elizabeth Van Every  
Head of Corporate Affairs  
Vanda Pharmaceuticals Inc.  
202-734-3400  
[pr@vandapharma.com](mailto:pr@vandapharma.com)

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