

**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 14, 2022 (December 13, 2022)**

**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:

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
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.

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**Item 8.01. Other Events.**

On December 13, 2022, Vanda Pharmaceuticals Inc. (the “Company”) issued a press release responding to the ruling of the United States District Court for the District of Delaware (the “Court”) in the Company’s patent litigation involving its product HETLIOZ®.

The full text of the press release responding to the Court’s ruling is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**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 December 13, 2022.</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: December 14, 2022

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel  
and Secretary



## **Vanda Pharmaceuticals Responds to Ruling in HETLIOZ® ANDA Litigation**

WASHINGTON, December 13, 2022 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today responded to the ruling in its HETLIOZ® ANDA Litigation.

Vanda has brought several Hatch-Waxman lawsuits in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. (Teva) and Apotex Inc. (Apotex) asserting infringement of patents covering HETLIOZ® (tasimelteon) 20 mg capsules. A trial was held in March 2022. Today the Court ruled that Teva and Apotex did not infringe U.S. Patent No. RE46,604, and that the asserted claims of U.S. Patent Nos. RE46,604; 9,730,910; 10,149,829; and 10,376,487 are invalid. Vanda intends to appeal the decision to the United States Court of Appeals for the Federal Circuit and to request a stay of market entry by Teva and Apotex while the appeal is pending.

HETLIOZ® is also approved in the European Union and is not subject to this litigation, nor is generic litigation pending outside of the United States. The litigation does not relate to the HETLIOZ LQ® oral suspension formulation.

### **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) and follow us on Twitter @vandapharma.

### **About HETLIOZ®**

For full U.S. Prescribing Information for HETLIOZ® and HETLIOZ LQ®, including indication and Important Safety Information, visit [www.hetlioz.com](http://www.hetlioz.com).

### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Various statements in this press release, including, but not limited to statements regarding Vanda's intention to appeal the decision and request a stay of market entry, are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, whether Vanda appeals the decision and Vanda's ability to obtain a stay of market entry. Therefore, no assurance can be given that the 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. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements",

“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, 2021, as updated by Vanda’s subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov).

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 press release is provided only as of the date of this press 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, except as required by law.

**Corporate Contact:**

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