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 14, 2022 (January 13, 2022)

VANDA PHARMACEUTICALS INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-34186**	**03-0491827**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(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 1.01. Entry into a Material Definitive Agreement.

On January 14, 2022, Vanda Pharmaceuticals Inc. ("Vanda") announced that it has entered into a License Agreement (the "License Agreement") with MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (together "MSN") and Impax Laboratories LLC ("Impax") settling Vanda's patent infringement litigation against MSN (the "Litigation") in the U.S. District Court for the District of Delaware (the "Court"). In the Litigation, Vanda alleges that MSN's Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of HETLIOZ® (tasimelteon) in the U.S. infringes certain U.S. patents owned by Vanda that cover HETLIOZ®.

In accordance with legal requirements, Vanda and MSN have agreed to submit the License Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. Vanda and MSN have also agreed to file stipulations of dismissal with the Court regarding the Litigation. The License Agreement provides for a full settlement of the claims that were asserted in the Litigation and includes a release by Vanda of all tasimelteon-related infringement claims against MSN and Impax based on conduct prior to the effective date of the License Agreement. The License Agreement also provides for the joint submission to the Court, for its approval, of a consent judgment enjoining MSN from making, using, selling, offering for sale, or importing into the U.S., the tasimelteon products that are the subject of MSN's ANDA except pursuant to a license from Vanda, and enjoining MSN from inducing or contributing to such infringement by others except pursuant to such a license from Vanda.

Under the License Agreement, Vanda granted MSN and Impax a non-exclusive license to manufacture and commercialize in the U.S. MSN's generic versions of the HETLIOZ® Products (as defined in the License Agreement) after the Trigger Date (as defined below).

Under the License Agreement, the "Trigger Date" is March 13, 2035, unless prior to that date Vanda obtains pediatric exclusivity for HETLIOZ®, in which case the Trigger Date will be July 27, 2035; however, MSN and Impax may be able to enter the market earlier under certain circumstances. Such circumstances relate to the resolution of any other third party HETLIOZ® patent litigation and the entry of certain other third-party generic versions of HETLIOZ®, among other events.

Vanda also agreed that if it enters into any similar agreements with other parties with respect to generic versions of HETLIOZ® that allow such other parties the right to sell generic versions of HETLIOZ® earlier than the date on which MSN and Impax are first permitted to sell MSN's generic version of HETLIOZ® under the License Agreement, then MSN and Impax will receive the benefit of such earlier date.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreement, which will be filed with the U.S. Securities and Exchange Commission (the "SEC") as an exhibit to Vanda's Quarterly Report on Form 10-Q for the fiscal quarter ending March 31, 2022.

The press release announcing the entry into the License Agreement and the settlement of the Litigation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated January 14, 2022.
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 14, 2022

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams
Name: Timothy Williams
Title: Senior Vice President, General Counsel and Secretary

Vanda Pharmaceuticals Settles HETLIOZ® Patent Litigation with MSN

WASHINGTON, January 14, 2022 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced it has entered into a License Agreement (the License Agreement) with MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (together MSN) and Impax Laboratories LLC (Impax) to resolve Vanda's patent litigation against MSN regarding MSN's Abbreviated New Drug Application seeking approval of its generic version of Vanda's HETLIOZ® (tasimelteon).

Under the License Agreement, Vanda granted MSN and Impax a non-exclusive license to manufacture and commercialize MSN's version of HETLIOZ® in the U.S. effective March 13, 2035, unless prior to that date Vanda obtains pediatric exclusivity for HETLIOZ®, in which case, the license will be effective July 27, 2035. MSN and Impax may enter the market earlier under certain limited circumstances.

The License Agreement is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The License Agreement provides for a full settlement and release by Vanda, MSN and Impax of all claims that are the subject of the litigation.

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 and follow us on Twitter @vandapharma.

About HETLIOZ®

HETLIOZ® (tasimelteon) is a melatonin receptor agonist. HETLIOZ® has been granted market authorization by the U.S. Food and Drug Administration and the European Medicines Agency. For full U.S. Prescribing Information for HETLIOZ®, including indication and Important Safety Information, visit www.hetlioz.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding the License Agreement, 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 regulatory authorities challenge the enforceability of or seek to enjoin the entry into the License Agreement, whether the U.S. District Court for the District of Delaware, where the litigation is pending, will grant orders dismissing the litigation, whether additional third parties may seek to market generic versions of HETLIOZ® and the results of any litigation that Vanda files to defend and/or assert its patents against such third parties. 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, 2020, 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.

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.

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