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 2, 2020 (December 1, 2020)

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

Delaware		
(State or other jurisdiction of incorporation)		
001-34186		**03-0491827**
(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 8.01. Other Events.

On December 1, 2020, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release announcing that the U.S. Food and Drug Administration (“FDA”) had approved HETLIOZ® (tasimelteon) capsule and liquid formulations for the treatment of adults and children, respectively, with nighttime sleep disturbances associated with Smith-Magenis Syndrome. The full text of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated December 1, 2020.
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 2, 2020

VANDA PHARMACEUTICALS INC.

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

FDA Approves HETLIOZ® (tasimelteon) for the Treatment of Nighttime Sleep Disturbances in Smith-Magenis Syndrome

WASHINGTON, December 1, 2020 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has approved HETLIOZ® (tasimelteon) capsule and liquid formulations for the treatment of adults and children, respectively, with nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS). SMS is a rare neurodevelopmental disorder, a defining feature of which is an "inverted" circadian rhythm, making it extremely difficult for patients with SMS to sleep during the night. HETLIOZ® is the first FDA-approved medication for patients with SMS.

"The FDA approval of HETLIOZ® for the treatment of nighttime sleep disturbances in SMS would not have been accomplished without the heroic efforts of SMS patients and the efforts of their families and advocates supporting the recruitment, design, and conduct of the study," said Mihael H. Polymeropoulos M.D., Vanda's President and CEO. "We remain committed to providing this much needed therapy to patients with SMS."

The approval of HETLIOZ® for the treatment of nighttime sleep disturbances in SMS was based on a single placebo-controlled efficacy study in this rare disorder, which studied both adults with SMS taking the HETLIOZ® capsule and children with SMS taking the liquid formulation. The safety profile of HETLIOZ® in this study was similar to those seen in HETLIOZ® studies previously conducted for the treatment of Non-24-Hour Sleep-Wake Disorder, and was similar between adults and children with SMS.

"We are very excited to see HETLIOZ®, the first ever treatment approved for people with SMS, addressing the significant problem of sleep disturbances and we are happy to see this treatment used in our community," said Maggie Miller, Co-Founder and Vice President of PRISMS (Parents and Researchers Interested in Smith-Magenis Syndrome). "We thank Vanda and the FDA for partnering to help our community and we look forward to continued partnership to bring this important therapy to families with SMS."

HETLIOZ® capsules, for adults with SMS, will be immediately available and the HETLIOZ LQ™ liquid formulation, for children with SMS, is expected to be available in the first quarter of 2021.

About Smith-Magenis Syndrome

Smith-Magenis Syndrome (SMS) is a developmental disorder that is caused by a small deletion of human chromosome 17p [1,2]. In more rare cases SMS is caused by a point mutation in the RAI1 gene which resides in the deleted region. SMS is estimated to affect 1/15,000-25,000 births in the U.S.[3] SMS is usually not inherited but rather is due to a de-novo deletion. Patients with SMS present with a number of physical, mental and behavioral problems. The most common symptom of SMS is a severe sleep disorder associated with significant disruption in the lives of patients and their families.

References:

1. Williams, S. R., Zies, D., Mullegama, S. V, Grotewiel, M. S., & Elsea, S. H. (2012). Smith-Magenis syndrome results in disruption of CLOCK gene transcription and reveals an integral role for RAI1 in the maintenance of circadian rhythmicity. Am.J Hum.Genet., 90(1537–6605), 941–949.

2. Gropman, A. L., Duncan, W. C., & Smith, A. C. (2006). Neurologic and developmental features of the Smith-Magenis syndrome (del 17p11.2). Pediatr.Neurol., 34(0887–8994), 337–350.

3. Orphanet ORPHA number 819.

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 release, including, but not limited to statements regarding Vanda's ability to make HETLIOZ® available to patients with nighttime sleep disturbances in SMS, 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, market acceptance of HETLIOZ® as a treatment of SMS in adults and children, Vanda's dependence on third-party manufacturers to manufacture HETLIOZ® in sufficient quantities and quality, and Vanda's sales and marketing infrastructure. 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 will be achieved. 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, 2019, 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.

Corporate Contact:

AJ Jones II
Chief Corporate Affairs and Communications Officer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Elizabeth Van Every
Head of Corporate Affairs
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com