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): May 13, 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 May 13, 2020, Vanda Pharmaceuticals Inc. ("Vanda") issued a press release relating to an agreement reached with the U.S. Food and Drug Administration regarding the resubmission by Vanda of the supplemental New Drug Application for the solid capsule formulation of HETLIOZ® for the treatment of adults with Smith-Magenis Syndrome ("SMS") and the New Drug Application for the liquid formulation of HETLIOZ® for the treatment of children with SMS. The full text of the press release is filed 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

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated May 13, 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: May 13, 2020

VANDA PHARMACEUTICALS INC.

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

Exhibit 99.1

Vanda Pharmaceuticals Announces Agreement with FDA on Resubmission of the Application for HETLIOZ® for the Treatment of Patients with Smith-Magenis Syndrome

WASHINGTON, May 13, 2020 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that following the completion of a Type A Meeting with the U.S. Food and Drug Administration (FDA) on May 8, 2020, it has reached agreement with the FDA to resubmit its application for HETLIOZ® (tasimelteon) for the treatment of Smith-Magenis Syndrome (SMS). As previously disclosed, Vanda received a Refusal to File letter from the FDA on March 12, 2020. The Type A Meeting resolved the outstanding issues regarding the filing of the application. Vanda plans to resubmit as soon as possible, seeking approval of the solid capsule formulation of HETLIOZ® for the treatment of adults with SMS, and the liquid formulation of HETLIOZ ® for the treatment of children with SMS*.

“We are very pleased with the outcome of the Type A Meeting,” said Dr. Mihael H. Polymeropoulos, President and CEO of Vanda. “This meeting was a great example of collaboration with the agency and we appreciate FDA’s thoughtful work in helping us advance the progress of our application and bring this potentially important treatment closer to use by patients with SMS.”

In December 2018, Vanda reported results of the largest placebo controlled study ever conducted in patients with SMS, with HETLIOZ® patients seeing significant improvements in sleep. SMS is a developmental disorder that is frequently caused by a small deletion of human chromosome 17p.[1, 2] In some cases, SMS is caused by a point mutation in the RAI1 gene, which resides in the deleted region. SMS is estimated to affect 1 in 15,000-25,000 individuals.[3] Patients with SMS present with a number of physical, mental and behavioral issues. The most common symptom of SMS is a severe sleep disorder, which results in significant disruption in the lives of patients and their families.

* Vanda’s resubmission will be in the form of a supplemental New Drug Application for the solid capsule formulation of HETLIOZ® for the treatment of adults with SMS (the sNDA) and a New Drug Application for the liquid formulation of HETLIOZ ® for the treatment of children with SMS (the NDA). Originally, Vanda submitted an sNDA covering both formulations, but the FDA requested that Vanda separate that application into an sNDA and an NDA for the different formulations.

References:

1. Williams, SR, Zies, D, Mullegama, SV, Grotewiel, MS, & Elsea, SH. 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. 2012; 90(1537–6605), 941–949.
2. Gropman, AL, Duncan, WC, & Smith, AC. Neurologic and developmental features of the Smith-Magenis syndrome (del 17p11.2). Pediatr Neurol. 2006; 34(0887–8994), 337–350.
3. Greenberg F, Guzzetta V, Montes de Oca-Luna R et al: Molecular analysis of the Smith –Magenis syndrome: a possible contiguous gene syndrome associated with del(17)(p11.2). Am J Hum Genet. 1991; 49:1207 – 1218.

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 Vanda’s Twitter and LinkedIn.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release, including, but not limited to statements regarding Vanda's HETLIOZ® program for the treatment of SMS and plans to resubmit the sNDA and the NDA related to such program, 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 ability to complete the preparation of and submit the sNDA and the NDA; the FDA's acceptance and review of such filings; Vanda's ability to obtain FDA approval of HETLIOZ® for the treatment of SMS in adults and children; 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, 2019 and quarterly report on Form 10-Q for the quarter ended March 31, 2020, which are on file with the SEC and available on the SEC's website at www.sec.gov. 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.