
**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): November 14, 2013

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:

- 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))
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Item 8.01. Other Events.

On November 14, 2013, Vanda Pharmaceuticals Inc. (the “Company” or “Vanda”) issued a press release regarding the results of a public U.S. Food and Drug Administration (“FDA”) Peripheral and Central Nervous System Drugs Advisory Committee (the “Committee”) meeting on November 14, 2013, which considered the Company’s pending New Drug Application (“NDA”) for tasimelteon, proposed tradename HETLIOZ™, for the treatment of Non-24-Hour Disorder (“Non-24”) in the totally blind, including a vote of the Committee recommending FDA approval of the Company’s tasimelteon NDA.

Vanda’s tasimelteon NDA is currently under Priority Review by the FDA for the treatment of Non-24 in the totally blind, with an action target date under the Prescription Drug User Fee Act (PDUFA-V) of January 31, 2014. For more information about the Committee hearing and the vote, please see the press release attached as Exhibit 99.1 to this Current Report on Form 8-K which is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated November 14, 2013.

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.

VANDA PHARMACEUTICALS INC.

By: /s/ James P. Kelly
Name: James P. Kelly
Title: Senior Vice President, Chief Financial
Officer, Secretary, and Treasurer

Dated: November 14, 2013

FDA Advisory Committee Recommends Approval of HETLIOZ™ for the Treatment of Non-24-Hour-Disorder (Non-24) in the Totally Blind***HETLIOZ™ is the First Potential Treatment to be Reviewed by the FDA for Non-24***

WASHINGTON, November 14, 2013 – Vanda Pharmaceuticals Inc. (VANDA) (NASDAQ: VNDA) announced today that the U.S. Food and Drug Administration's (FDA) Peripheral and Central Nervous System Drugs Advisory Committee (Advisory Committee) voted overwhelmingly to recommend the approval of Vanda's New Drug Application (NDA) for tasimelteon, proposed tradename HETLIOZ™, for the treatment of Non-24-Hour Disorder (Non-24) in the totally blind.

The advisory panel found that:

- Non-24 is an appropriate indication for an FDA-approved therapy;
- the clinical endpoints are appropriate to support the indication;
- there is substantial evidence of tasimelteon efficacy in Non-24; and
- and the safety of tasimelteon in Non-24 has been adequately addressed.

“We are extremely pleased that the FDA's advisory committee has recommended that the FDA approve HETLIOZ™ for the treatment of Non-24 in the totally blind,” said Mihael H. Polymeropoulos M.D., Vanda's President and Chief Executive Officer. “We are now one step closer toward our goal of providing a treatment option that addresses the physiologic cause of this serious, debilitating orphan condition that impacts a majority of totally blind individuals.”

Vanda's tasimelteon NDA is currently under Priority Review by the FDA for the treatment of Non-24 in the totally blind, with an action target date under the Prescription Drug User Fee Act (PDUFA-V) of January 31, 2014.

The FDA grants Priority Review status for a “drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness” over current therapies. Currently, there is no approved treatment for Non-24 and HETLIOZ™ has the potential to address this unmet medical need.

About Non-24-Hour Disorder

Non-24 is a serious, rare, and chronic circadian rhythm disorder characterized by the inability to entrain (synchronize) the master body clock with the 24-hour day-night cycle. Non-24 affects a majority of totally blind individuals, or between 65,000 and 95,000 people in the U.S. Non-24 occurs almost entirely in individuals who lack the light sensitivity necessary to entrain the master body clock in the brain with the 24-hour day-night cycle. Most people have a master body clock that naturally runs longer than 24-hours and light is the primary environmental cue that resets it to 24 hours each day. Individuals with Non-24 have a master body clock that is not reset, and continually delays, resulting in prolonged periods of misalignment between their circadian rhythms and the 24-hour day-night cycle, including the timing of melatonin and cortisol secretion. As a result of this misalignment, Non-24 is associated with significant disruption of the sleep-wake cycle and impairments in social and occupational functioning, and marked subjective distress. Currently there is no approved treatment for Non-24. For more information on Non-24, please visit www.Non-24.com.

About Tasimelteon

Tasimelteon, proposed tradename HETLIOZ™, is a circadian regulator in development for the treatment of Non-24. Tasimelteon is a dual melatonin receptor agonist (DMRA) with selective agonist activity at the MT1 and MT2 receptors. Tasimelteon aims to reset the master body clock in the suprachiasmatic nucleus (SCN), resulting in the entrainment of the body's melatonin and cortisol rhythms to align to the 24-hour day-night cycle. The patent claiming Tasimelteon as a new chemical entity extends through December 2022, assuming a 5-year extension to be granted under the Hatch-Waxman Act. Tasimelteon has been granted orphan drug designation for the treatment of Non-24 from both the U.S. and the European Union. Tasimelteon has not been approved by the FDA or any other regulatory authority.

About Vanda Pharmaceuticals Inc.

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. For more on Vanda, please visit <http://www.vandapharma.com>.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release are “forward-looking statements” under the securities laws. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “project,” “target,” “goal,” “likely,” “will,” “would,” and “could,” or the negative of these terms and similar expressions or words, identify forward-looking statements. 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 the company’s forward-looking statements include, among others: the FDA not following the Advisory Committee’s recommendation, Vanda’s failure to obtain, or any delay in

obtaining, regulatory approval for tasimelteon for the treatment of Non-24-Hour Disorder or to comply with ongoing regulatory requirements 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, 2012 and quarterly report on Form 10-Q for the quarter ended September 30, 2013, 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.

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