
**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 31, 2014

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 January 31, 2014, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release announcing that the U.S. Food and Drug Administration (“FDA”) had approved HETLIOZ™ (tasimelteon) 20mg capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (“Non-24”). The full text of this press release is furnished as Exhibit 99.1 to this Form 8-K.

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 January 31, 2014. |

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: January 31, 2014

**FDA APPROVES HETLIOZ™ (TASIMELTEON) FOR THE TREATMENT OF
NON-24-HOUR SLEEP-WAKE DISORDER**

Non-24 is highly prevalent among the totally blind

WASHINGTON, January 31, 2014 --PRNewswire/— Vanda Pharmaceuticals Inc. (VANDA) (NASDAQ: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has approved HETLIOZ™ (tasimelteon) 20mg capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24). HETLIOZ™ is the first FDA approved medication for Non-24.

Non-24 was first described more than 60 years ago, and is a chronic, circadian rhythm disorder resulting from the misalignment of the endogenous master body clock to the 24-hour day, disrupting the sleep-wake cycle. Non-24 affects the majority of totally blind individuals and it is estimated that approximately 80,000 Americans have the disorder.

“The FDA approval of HETLIOZ™ would not have been accomplished without the heroic efforts of blind patients and their advocates,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and Chief Executive Officer. “We are committed to providing much needed support to patients with Non-24 and facilitating access to this new therapeutic option.”

The approval of HETLIOZ™ was based on two key efficacy studies and the safety has been evaluated in over 1,300 individuals.

The most common adverse reactions in the clinical trials were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. After taking HETLIOZ™, patients should limit their activity to preparing for going to bed because HETLIOZ™ can impair the performance of activities requiring complete mental alertness.

“Totally blind people have struggled with the problems brought on by Non-24-Hour Sleep-Wake Disorder, sometimes for their entire life, without understanding what causes it and without being able to do anything about it” said Steven W. Lockley, Ph.D., Division of Sleep Medicine, Brigham and Women’s Hospital, a teaching affiliate of Harvard Medical School. “Today’s FDA approval of HETLIOZ™ means that, for the first time, these patients have access to an approved, safe and effective treatment for their difficult debilitating disorder.”

Vanda anticipates making HETLIOZ™ commercially available in the second quarter of 2014.

Conference Call for Investors

Vanda Pharmaceuticals will host a conference call for investors, Monday, February 3, 2014 at 10:00 AM ET, to discuss the FDA’s approval of HETLIOZ™. Investors can call 1-888-895-5271 (domestic) and 1-847-619-6547 (international) and use passcode 36581091. A replay of the call will be available beginning Monday, February 3, 2014 at 12:30 PM ET and will be accessible until Monday, February 10, 2014, at 11:59 PM ET. The replay call-in number is 1-888-843-7419 for domestic callers and 1-630-652-3042 for international callers. The access number is 36581091.

The conference call will be broadcast simultaneously on Vanda’s website, www.vandapharma.com. Investors should click on the Investor Relations tab and are advised

to go to the website at least 15 minutes early to register, download, and install any necessary software or presentations. The call will also be archived on Vanda's website for a period of 30 days.

About HETLIOZ™

Full HETLIOZ™ Prescribing Information can be found at: www.hetlioz.com

For more information about HETLIOZ™ call 1-844-HETLIOZ (1-844-438-5469).

Indication and Important Safety Information About HETLIOZ™

Indication

HETLIOZ™ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

Important Safety Information

HETLIOZ™ may cause somnolence: After taking HETLIOZ™, patients should limit their activity to preparing for going to bed, because HETLIOZ™ can impair the performance of activities requiring complete mental alertness.

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ™ than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ™ is increased by approximately 2-fold compared with younger patients.

Use of HETLIOZ™ should be avoided in combination with fluvoxamine or other strong CYP1A2 inhibitors, because of a potentially large increase in exposure of HETLIOZ™, and a greater risk of adverse reactions. HETLIOZ™ should be avoided in combination with rifampin or other CYP3A4 inducers, because of a potentially large decrease in exposure of HETLIOZ™, with reduced efficacy.

There are no adequate and well-controlled studies of HETLIOZ™ in pregnant women. Based on animal data, HETLIOZ™ may cause fetal harm. HETLIOZ™ should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZ™ is administered to a nursing woman.

HETLIOZ™ has not been studied in patients with severe hepatic impairment and is not recommended in these patients.

Safety and effectiveness of HETLIOZ™ in pediatric patients have not been established.

Full HETLIOZ™ Prescribing Information can be found at: www.hetlioz.com

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 www.vandapharma.com.

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 Vanda’s forward-looking statements include, among others: Vanda’s ability to successfully commercialize (alone or with others) HETLIOZ™ in the U.S., uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ™, Vanda’s dependence on third-party manufacturers to manufacture HETLIOZ™ in sufficient quantities and quality, Vanda’s limited sales and marketing infrastructure, 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 which is 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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U.S. full prescribing information for HETLIOZ™ is available at www.HETLIOZ.com

HETLIOZ™ is a registered trademark of Vanda Pharmaceuticals Inc.

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