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): April 24, 2015

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:

☐ 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))

Item 8.01. Other Events.

On April 24, 2015, Vanda Pharmaceuticals Inc. issued a press release announcing that the European Medicines Agency's Committee for Medicinal Product for Human Use had adopted a positive opinion recommending approval of HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder in totally blind adults in the European Union. A copy of the press release is filed as Exhibit 99.1 hereto 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 April 24, 2015.

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.

Dated: April 24, 2015

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

Exhibit 99.1

Vanda Receives Positive CHMP Opinion for HETLIOZ® (tasimelteon) for the Treatment of Non-24-Hour Sleep-Wake Disorder in the European Union

- HETLIOZ®, a circadian regulator, is the first and only product to receive a recommendation for approval for Non-24 in the European Union
- The European Medical Agency is expected to make its final decision in approximately two months

WASHINGTON, April 24, 2015/PRNEWSWIRE/ — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending approval of HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in totally blind adults in the European Union (EU).

"The positive opinion by CHMP on HETLIOZ® is another milestone on the road to approval in the EU and the building of a global brand to benefit patients with Non-24 throughout the world," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO.

The CHMP positive opinion will be reviewed by the European Commission (EC). If approved, the EC grants a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the EU, as well as European Economic Area members Iceland, Liechtenstein and Norway. The EC usually issues a final decision within two months of a CHMP opinion.

In 2011, HETLIOZ® was granted orphan drug designation for the treatment of Non-24 in blind people with no light perception from the EC. HETLIOZ® was approved by the U.S. Food and Drug Administration in January 2014 and is available through specialty pharmacies in the U.S.

About the CHMP Positive Opinion for HETLIOZ® (from EMA release)

Summary of opinion[1] (initial authorisation)

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product HETLIOZ®, intended for the treatment of non-24-hour sleep-wake disorder in totally blind adults. HETLIOZ® was designated as an orphan medicinal product on 23 February 2011. The applicant for this medicinal product is Vanda Pharmaceuticals Ltd.

HETLIOZ® will be available as 20 mg hard capsules. The active substance of HETLIOZ® is tasimelteon, a psycholeptic (ATC code: N05CH03). Tasimelteon is a melatonin receptor agonist and acts as a circadian regulator that resets the master body clock in the suprachiasmatic nucleus.

The benefit with HETLIOZ® is its ability to entrain the master body clock in patients with non-24-hour sleep-wake disorder. The most common side effects are headache, somnolence, and nightmares or unusual dreams.

The full indication is: "HETLIOZ® is indicated for the treatment of non-24-hour sleep-wake disorder (non-24) in totally blind adults".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

(1) Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

The announcement of the CHMP positive opinion for HETLIOZ® can be found on the EMA website at http://www.ema.europa.eu.

About Non-24-Hour Sleep-Wake Disorder

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. The sleep disturbance causes significant distress or impairment in social, occupational and other important areas of functioning. Non-24 affects the majority of totally blind individuals and it has been estimated that approximately 130,000 people in the European Union have the disorder.

About HETLIOZ®

HETLIOZ® is a melatonin receptor agonist. HETLIOZ® has been approved by the U.S. Food and Drug Administration for the treatment of Non-24. For full U.S. prescribing information, please visit www.hetlioz.com.

U.S. Indication and Important Safety Information About HETLIOZ®

Indication

HETLIOZ® is indicated for the treatment of 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 U.S. 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. 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 assumptions regarding the regulatory status of HETLIOZ® in the European Union 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, 2014, 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

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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