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): July 7, 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 July 7, 2015, Vanda Pharmaceuticals Inc. issued a press release announcing that the European Commission had approved HELTIOZ® (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 July 7, 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: July 7, 2015

By: /s/ James P. Kelly

Name: James P. Kelly

Title: Senior Vice President, Chief Financial Officer, Secretary, and Treasurer

Exhibit 99.1

HETLIOZ® Receives European Commission Approval for the Treatment of Non-24-Hour Sleep-Wake Disorder in the Totally Blind

- HETLIOZ®, a circadian regulator, is the first and only product to receive approval for Non-24 in the European Union

WASHINGTON, July 7, 2015 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced that the European Commission (EC) approved HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in totally blind adults in the European Union (EU).

“The European approval of HETLIOZ is an important milestone for the Non-24 patients throughout the European Union who live with this debilitating disorder,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO.

The marketing authorization allows for the marketing of HETLIOZ® in all 28 EU member states as well as European Economic Area members Iceland, Liechtenstein and Norway. The EC has also confirmed orphan drug designation for HETLIOZ® for the treatment of Non-24 in totally blind adults.

About Non-24-Hour Sleep-Wake Disorder

Non-24 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 and/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 and acts as a circadian regulator that resets the master body clock in the suprachiasmatic nucleus in the brain. The benefit with HETLIOZ® is its ability to entrain the master body clock in patients with Non-24. Detailed recommendations for the use of this product are described in the summary of product characteristics (SmPC), which is published in the European public assessment report (EPAR) and available in all official European Union languages. Upon the EC public announcement of the HETLIOZ® approval, complete EU prescribing information for HETLIOZ® will be available at http://www.ema.europa.eu.

About HETLIOZ® Development

The EC approval was based on data from the HETLIOZ® clinical development program, the largest clinical research program ever conducted in Non-24. The clinical development program included two pivotal Phase 3 clinical trials, SET (Safety and Efficacy of Tasimelteon) and RESET (Randomized-withdrawal study of the Efficacy and Safety of Tasimelteon to treat Non-24).

EU Indication and Usage

HETLIOZ® is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in totally blind adults

Indication and Important Safety Information About HETLIOZ® for EU Patients

HETLIOZ® may cause somnolence: After taking HETLIOZ®, patients should limit their activity to preparing for going to bed. The most common adverse reactions (incidence >3%) during clinical trials were headache, somnolence, nausea, and dizziness. The most frequently reported adverse reactions were mostly mild to moderate in severity and transient in nature.

Caution should be used when administering HETLIOZ® in combination with fluvoxamine or other strong CYP1A2 inhibitors such as ciprofloxacin and enoxacin, 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. Caution should be used when administering HETLIOZ® in combination with omeprazole or other strong CYP2C19 inhibitors because their potential to increase tasimelteon exposure has not been studied.

HETLIOZ® contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. HETLIOZ® capsules contain the azo coloring agent Orange Yellow S (E110), which may cause allergic reactions

HETLIOZ® has not been studied in pregnant women. 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 children and its effects are unknown. HETLIOZ® is not recommended 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.

Upon the EC public announcement of the HETLIOZ® approval, complete EU prescribing information for HETLIOZ® will be available at http://www.ema.europa.eu.

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 ability to successfully commercialize (alone or with others) HETLIOZ® in the EU, uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ® in the EU, assumptions regarding the long-term effects of HETLIOZ®, 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 and quarterly report on Form 10-Q for the quarter ended March 31, 2015, 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.

HETLIOZ® is a registered trademark of Vanda Pharmaceuticals Inc.

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