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): June 3, 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.)

П

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)

k 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 sions:
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 June 3, 2014, Vanda Pharmaceuticals Inc. (the "Company" or "Vanda") issued a press release regarding the European Medicines Agency's acceptance for evaluation of Vanda's Marketing Authorization Application for oral HETLIOZTM (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder. 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	
Nο	

Description

99.1 Press release of Vanda Pharmaceuticals Inc. dated June 3, 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: June 3, 2014

European Medicines Agency Accepts HETLIOZTM (tasimelteon) Marketing Authorization Application for Non-24-Hour Sleep-Wake Disorder in the Totally Blind

WASHINGTON, June 3, 2014/PRNEWSWIRE/ — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) announced today that its Marketing Authorization Application (MAA) for oral HETLIOZTM (tasimelteon) capsules has been accepted for evaluation by the European Medicines Agency (EMA) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

"The EMA submission is an important milestone towards providing a treatment option for people living with Non-24 in the European Union," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "This continues our efforts to expand the availability of HETLIOZ to markets outside the U.S."

HETLIOZ™ has been granted orphan drug designation for the treatment of Non-24 in blind people with no light perception from the European Commission. HETLIOZ™ was approved by the FDA in January 2014 and is available through specialty pharmacies in the U.S.

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 is estimated that approximately 130,000 people in the European Union have the disorder.

About HETLIOZTM

HETLIOZ™ is a melatonin receptor agonist. HETLIOZ™ has been approved by the U.S. Food and Drug Administration for the treatment of Non-24-Hour Sleep-Wake Disorder (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-Hour Sleep-Wake Disorder (Non-24).

Important Safety Information

HETLIO Z^{TM} may cause somnolence: After taking HETLIO Z^{TM} , patients should limit their activity to preparing for going to bed, because HETLIO Z^{TM} 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 HETLIOZTM in pregnant women. Based on animal data, HETLIOZTM may cause fetal harm. HETLIOZTM should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZTM 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. 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: the regulatory status of tasimelteon in Europe, the prevalence of Non-24 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, 2013 and quarterly report on Form 10-Q for the quarter ended March 31, 2014, 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.

U.S. full prescribing information for HETLIOZTM is available at <u>www.HETLIOZ.com</u>.

 $HETLIOZ^{\text{TM}}$ is a registered trademark of Vanda Pharmaceuticals Inc.

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