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 29, 2013

VANDA PHARMACEUTICALS INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-34186**	**03-0491827**
(State or other Jurisdiction of Incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

2200 Pennsylvania Avenue NW
Suite 300E
Washington, DC **20037**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's telephone number, including area code: (202) 734-3400

N/A
(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 29, 2013, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release announcing the U.S. Food and Drug Administration’s acceptance and priority review of Vanda’s New Drug Application for tasimelteon for the treatment of Non-24-Hour Disorder in the totally blind. 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 29, 2013.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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: July 29, 2013

Exhibit 99.1

FDA ACCEPTS TASIMELTEON NEW DRUG APPLICATION FOR PRIORITY REVIEW IN THE TREATMENT OF NON-24-HOUR DISORDER IN THE TOTALLY BLIND

WASHINGTON, July 29, 2013 – Vanda Pharmaceuticals Inc. (VANDA) (NASDAQ: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has accepted the filing and granted a priority review classification to Vanda's New Drug Application (NDA) for tasimelteon, a circadian regulator for the treatment of Non-24-Hour Disorder (Non-24) in the totally blind.

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[1]. Currently, there is no approved treatment for Non-24 and tasimelteon has the potential to address this unmet medical need.

"We are extremely pleased that the FDA has granted tasimelteon priority review for the treatment of Non-24 in the totally blind," said Mihael H. Polymeropoulos M.D., Vanda's President and Chief Executive Officer. "The agency's acceptance of the NDA and decision to place tasimelteon in a category of expedited review are important milestones for Vanda as we take another step toward our goal of providing patients with a treatment for Non-24."

The FDA determined the action target date under Prescription Drug User Fee Act (PDUFA-V), to be January 31, 2014. The FDA has also tentatively scheduled an advisory committee meeting to discuss the tasimelteon application on November 14, 2013.

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 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 Tasimelteon NDA

Summary of Efficacy

The efficacy of tasimelteon as a circadian regulator of the master body clock in the treatment of Non-24 was studied in two randomized, double-masked, placebo-controlled, multicenter, parallel-group trials, SET (Safety and Efficacy of Tasimelteon) and RESET (Randomized withdrawal Study of the Efficacy and safety of Tasimelteon). In the SET study, tasimelteon achieved the primary endpoints of entrainment (synchronizing) of the melatonin rhythm and clinical response as measured by entrainment plus an improvement on the Non-24 Clinical Response Scale. Tasimelteon also demonstrated statistically significant improvement in measures of nighttime sleep, daytime nap duration, timing of sleep, and overall global functioning scale. In patients treated with tasimelteon, daytime naps decreased by 46 minutes per day in the worst 25% of days in a cycle and nighttime sleep increased by 57 minutes per day during the worst 25% of nights in a cycle. The RESET study demonstrated that patients who continued treatment with 20 mg of tasimelteon maintained entrainment of melatonin and cortisol circadian rhythms at statistically significantly greater percentages than patients receiving placebo. Patients treated with tasimelteon also maintained their clinical benefits while patients who received placebo showed significant deterioration in measures of nighttime sleep, daytime naps and timing of sleep.

Summary of Safety

The Integrated Summary of Safety (ISS) for the tasimelteon development program included data from over 1,300 subjects treated with tasimelteon including 111 subjects treated for at least six months and 44 subjects treated for at least one year. Common adverse events (>=2% in tasimelteon and greater than placebo) in placebo controlled studies (tasimelteon n=429, placebo n=203) included, (tasimelteon %, placebo %), Back pain (2.1%, 2.0%), Dreams (vivid or unusual), (2.6%, 0.5%), Diarrhea (2.3%, 1.0%), Dry Mouth (2.3%, 0.5%), Headache (9.6%, 7.4%), Nasopharyngitis (6.5%, 6.4%), Somnolence (3.0%, 1.5%), Upper Respiratory Tract Infection (2.6%, 1.5%). In placebo controlled studies (tasimelteon n=429, placebo n=203), all serious adverse events were deemed unrelated to study drug and the rates between tasimelteon and placebo treated patients were similar (1.6%, 1.5%).

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 FORWWARD 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: 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 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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[1] U.S. Department of Health and Human Services Food and Drug Administration, “Draft Guidance for Industry: Expedited Programs for Serious Conditions —Drugs and Biologics” June 2013. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf [Last accessed June 22, 2013]