# 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): March 25, 2013

### 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
(Address of Principal Executive Offices)

20037 (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 March 25, 2013, Vanda Pharmaceuticals Inc. issued a press release regarding its recent pre-NDA meeting with the U.S. Food and Drug Administration. 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 March 25, 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: March 25, 2013

## VANDA REPORTS SUCCESSFUL COMPLETION OF PRE-NDA MEETING WITH FDA ON TASIMELTEON FOR THE TREATMENT OF NON-24-HOUR DISORDER IN THE TOTALLY BLIND

WASHINGTON, March 25, 2013 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ:VNDA) today announced that the company held a pre-NDA meeting with the Division of Neurology Products of the U.S. Food and Drug Administration (FDA) to discuss the regulatory path for filing a New Drug Application (NDA) for tasimelteon, a circadian regulator, for the treatment of Non-24-Hour Disorder (Non-24). Non-24 is a serious, rare circadian rhythm disorder that affects a majority of totally blind individuals. Currently there is no FDA approved treatment for Non-24.

At the pre-NDA meeting, the FDA confirmed that the efficacy and safety data proposed by Vanda to be submitted in the tasimelteon NDA for Non-24 is adequate to support filing. The NDA supporting package that includes data from clinical pharmacology, pre-clinical pharmacology program, chemistry and manufacturing was also deemed adequate to support filing.

"We are pleased with the positive interaction we had with the FDA as we are moving closer to providing a treatment for blind individuals with Non-24," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda.

Based on this successful completion of the pre-NDA meeting, Vanda is targeting an NDA submission for tasimelteon in mid-2013.

### **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 <a href="https://www.vandapharma.com">www.vandapharma.com</a>.

### **Company Contact:**

Jim Kelly Senior Vice President and Chief Financial Officer Vanda Pharmaceuticals Inc. (202) 734-3428 jim.kelly@vandapharma.com

### **Media Contact:**

Laney Cohen Account Supervisor Makovsky & Company, Inc. (212)-508-9643 lcohen@makovsky.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 the company's forward-looking statements include, among others: the inability to reach agreement with the FDA regarding Vanda's regulatory approval strategy or proposed path to approval for tasimelteon for the treatment of Non-24-Hour Disorder; Vanda's failure to obtain 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 <a href="https://www.sec.gov">www.sec.gov</a>. 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.