# 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): January 31, 2013

# VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation)

> 2200 Pennsylvania Avenue NW Suite 300E Washington, DC (Address of Principal Executive Offices)

001-34186 (Commission File No.) 03-0491827 (IRS Employer Identification No.)

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))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

# Item 8.01 Other Events

On January 31, 2013, Vanda Pharmaceuticals Inc. issued a press release announcing the results from its tasimelteon MAGELLAN Phase IIb/III efficacy study for Major Depressive 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<br>No. | Description   |
|----------------|---|
| 99.1           | Press Release of Vanda Pharmaceuticals Inc. dated January 31, 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. KellyTitle:Senior Vice President, Chief Financial Officer,<br/>Secretary, and Treasurer

Dated: January 31, 2013

#### VANDA ANNOUNCES PHASE IIB/III CLINICAL STUDY IN MAJOR DEPRESSIVE DISORDER DID NOT MEET THE PRIMARY ENDPOINT

WASHINGTON, January 31, 2013 /PRNewswire/ — Vanda Pharmaceuticals Inc. (NASDAQ:VNDA) today announced top-line results of the Phase IIb/III clinical study (MAGELLAN) in Major Depressive Disorder (MDD), investigating the efficacy and safety of tasimelteon as a monotherapy in the treatment of patients with MDD. The clinical study did not meet the primary endpoint of change from baseline in the Hamilton Depression Scale (HAMD-17) after 8 weeks of treatment as compared to placebo. Both tasimelteon and placebo treated patients had an approximately 40% reduction of their MDD symptoms from baseline. Tasimelteon was shown to be safe and well-tolerated, consistent with observations in prior studies. Given these current proof of concept clinical study results, Vanda has decided to discontinue all activities in this indication.

"These results are disappointing, as there is still a significant unmet medical need for patients with Major Depression" said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. "Tasimelteon's application in the treatment of blind individuals with Non-24 remains our top priority as we pursue our planned NDA submission this year."

Vanda has recently reported positive results in two phase III clinical studies of tasimelteon in Non-24- Hour Disorder (Non-24) and plans to submit a New Drug Application to the U.S. Food and Drug Administration in mid-2013.

#### About MAGELLAN

MAGELLAN was a proof of concept, two arm (tasimelteon 20mg and placebo), 8-week, double-masked, randomized, phase IIb/III clinical study in patients with MDD. The study enrolled 507 patients in 43 sites in the U.S. The primary endpoint of the study was the change from baseline in the Hamilton Depression Scale (HAMD-17) at week 8.

#### **About Tasimelteon**

Tasimelteon is a circadian regulator in development for the treatment of Non-24. Tasimelteon is a melatonin agonist of the human  $MT_1$  and  $MT_2$  receptors, with greater specificity for  $MT_2$ . Tasimelteon's ability to reset the master body clock in the suprachiasmatic nucleus (SCN), located in the hypothalamus, results in the entrainment of the body's melatonin and cortisol rhythms to align to the 24-hour day-night cycle. Tasimelteon is currently in Phase III development for Non-24. A New Drug Application, is expected to be submitted to the U.S. Food and Drug Administration in mid-2013 for Non-24.

#### **Conference Call**

Vanda has scheduled a conference call for today, Thursday, January 31, 2013 at 9 AM ET to discuss the MDD clinical trial results. Investors can call 1-888-895-5479 (domestic) and 1-847 619-6250 (international) and use passcode 34186999. A replay of the call will be available beginning Thursday, January 31, 2013, at 11:30 AM ET and will be accessible until Thursday, February 7, 2013, at 11:59 PM ET. The replay call-in number is 1-888-843-7419 for domestic callers and 1-630 652-3042 for international callers. The access number is 34186999. The conference call will be broadcast simultaneously on Vanda's website, <u>http://www.vandapharma.com</u>. Investors should click on the Investor Relations tab and are advised to go to the website at least 15 minutes early to register, download and install any necessary software. The call will also be archived on Vanda's website for a period of 30 days, through March 2, 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 <u>http://www.vandapharma.com</u>.

#### Company Contact:

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#### 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, 2011 which is on file with the SEC and available on the SEC's website at <u>www.sec.gov</u>. 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.