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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 23, 2013**

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**VANDA PHARMACEUTICALS INC.**

(Exact name of Registrant as specified in its charter)

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**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)

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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))
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**Item 8.01 Other Events**

On January 23, 2013, Vanda Pharmaceuticals Inc. issued a press release announcing the results from its RESET Phase III study. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated by reference herein.

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**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

**Exhibit  
No.**

**Description**

99.1 Press Release of Vanda Pharmaceuticals Inc. dated January 23, 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: January 23, 2013

**VANDA ANNOUNCES POSITIVE RESULTS IN THE SECOND PHASE III STUDY (RESET) OF TASIMELTEON FOR THE TREATMENT OF NON-24-HOUR DISORDER**

- *Tasimelteon significantly maintains entrainment of circadian rhythms*
- *Discontinuation of tasimelteon results in significant clinical deterioration*

WASHINGTON, January 23, 2013 /PRNewswire/ — Vanda Pharmaceuticals Inc. (NASDAQ:VNDA), today announced positive results for the second Phase III study of tasimelteon for the treatment of Non-24-Hour Disorder (Non-24). The RESET study (Randomized-withdrawal study of the Efficacy and Safety of Tasimelteon to treat Non-24-Hour Disorder), demonstrated the maintenance effect of 20mg of tasimelteon to entrain melatonin and cortisol circadian rhythms in individuals with Non-24. Tasimelteon treated patients maintained their clinical benefits while placebo treated patients showed significant deterioration in measures of nighttime sleep, daytime naps, and timing of sleep. Non-24 is a serious, rare circadian rhythm disorder that affects a majority of totally blind individuals who lack light perception and cannot entrain (reset) their master body clock to the 24-hour day. Currently there is no approved treatment for Non-24.

“These results clearly demonstrate that tasimelteon can entrain the circadian clock and continued treatment is necessary to maintain entrainment,” said Steven W. Lockley, Ph.D., Division of Sleep Medicine, Brigham and Women’s Hospital, a teaching affiliate of Harvard Medical School. “The study also shows that entrainment is associated with meaningful clinical benefits and that maintaining entrainment of the master body clock is critical to treating the problems caused by Non-24.”

“We are excited by these results as they move us one step closer towards providing a treatment for blind individuals with Non-24,” said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. “These results also highlight the importance of chronic therapy in treating Non-24. We are confident that if approved, tasimelteon may significantly improve the quality of life for individuals with Non-24.”

**RESET Study Results Summary****Primary Endpoint**

The RESET study was a 20 patient randomized withdrawal study designed to demonstrate the maintenance effect of 20mg of tasimelteon in the treatment of blind individuals with Non-24. Patients were treated with tasimelteon for three months during an open-label run-in phase. Patients who responded to tasimelteon treatment during the run-in phase, as measured by entrainment of the melatonin rhythm (aMT6s) to the 24-hour day, were then randomized to receive either placebo or continue receiving tasimelteon 20mg for 2 months. The primary endpoint of the study was the maintenance of effect as measured by entrainment of the melatonin (aMT6s) rhythm.

## **Primary Endpoint Results**

	<u>Tasimelteon</u>	<u>Placebo</u>	<u>p-value</u>
Maintenance of entrainment (aMT6s) (%)	90.0	20.0	0.0026

## **Secondary Endpoints**

The RESET study also assessed a number of secondary endpoints including maintenance of entrainment of the cortisol rhythm and a range of sleep and wake parameters including LQ-nTST (total nighttime sleep in the worst 25% of nights), UQ-dTSD (total daytime sleep duration in the worst 25% of days) and MoST (midpoint of sleep timing from both nighttime and daytime sleep).

## **Secondary Endpoint Results**

	<u>Tasimelteon</u>	<u>Placebo</u>	<u>Difference</u>	<u>p-value</u>
Maintenance of entrainment (cortisol) (%)	80.0	20.0	60.0	0.0118
LQ-nTST (LS mean minutes) <sup>1</sup>	-6.6	-73.8	67.2	0.0233
UQ-dTSD (LS mean minutes) <sup>2</sup>	-9.6	49.8	-59.4	0.0266
MoST (LS mean minutes) <sup>1</sup>	19.8	-16.2	36.0	0.0108

- 1) Higher number indicates improvement
- 2) Lower number indicates improvement

From the run-in phase of the study, the rate of entrainment among tasimelteon treated patients ranged from 50% to 85% based on individual patient characteristics. In a time to relapse analysis (45 min decrement of weekly average nighttime sleep), placebo treated patients relapsed in higher numbers and at an earlier time than tasimelteon treated patients (P = 0.0907).

The RESET study demonstrates the efficacy of chronic treatment with tasimelteon in Non-24 and further supports the results of the SET study, which established the ability of tasimelteon to entrain the master body clock and significantly improve the clinical symptoms of Non-24. Vanda plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in mid-2013. Vanda will meet with the FDA in Q1 of 2013 for a pre-NDA meeting on tasimelteon in the treatment of patients with Non-24.

## **About Non-24-Hour Disorder**

Non-24-Hour Disorder (Non-24) is a serious, rare, and chronic circadian rhythm disorder that affects a majority of totally blind individuals in the U.S., or between 65,000 and 95,000 people. Tasimelteon has been granted orphan drug designation for the treatment of Non-24 from both the U.S. and the European Union. Non-24 occurs almost entirely in individuals who lack the light sensitivity necessary to entrain, or synchronize, 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 continually delays, putting them to sleep later and later each day, turning night into day and day into night, until the cycle starts all over again. This circadian disorder is highly disruptive, making it difficult to do well in school, hold down a job or maintain relationships. For more information on Non-24, please visit <http://Non-24.com>.

### **About Tasimelteon**

Tasimelteon is a circadian regulator in development for the treatment of Non-24. Tasimelteon is a melatonin agonist of the human MT<sub>1</sub> and MT<sub>2</sub> receptors, with greater specificity for MT<sub>2</sub>. 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 and Phase IIb/III for Major Depressive Disorder (MDD).

### **Conference Call**

Vanda has scheduled a conference call for today, Wednesday, January 23, 2013 at 9 AM ET to discuss the trial results. Investors can call 1-866-713-8565 (domestic) and 1-617-597-5324 (international) and use passcode 60037962. A replay of the call will be available beginning Wednesday, January 23, 2013, at 11:00 AM ET and will be accessible until Wednesday, January 30, 2013, at 11:59 PM ET. The replay call-in number is 1-888-286-8010 for domestic callers and 1-617-801-6888 for international callers. The access number is 97367748.

The conference call will be broadcast simultaneously on Vanda's website, <http://www.vandapharma.com>. 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 February 21, 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 <http://www.vandapharma.com>.

### **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; the failure of Vanda’s clinical trials to demonstrate the safety and/or efficacy of tasimelteon in the treatment of Major Depressive Disorder; 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 [www.sec.gov](http://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.