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): December 18, 2012

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 December 18, 2012, Vanda Pharmaceuticals Inc. issued a press release announcing the results from its Safety and Efficacy of Tasimelteon (SET) Phase III study. 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 December 18, 2012.

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: December 18, 2012

Exhibit 99.1

VANDA ANNOUNCES POSITIVE PHASE III RESULTS FOR TASIMELTEON IN THE TREATMENT OF NON-24-HOUR DISORDER

- ***Tasimelteon is shown to entrain the master body clock as measured by melatonin and cortisol circadian rhythms***
- ***Tasimelteon is shown to significantly improve clinical symptoms across a number of sleep and wake measures***

WASHINGTON, D.C., December 18, 2012, /PRNewswire/— Vanda Pharmaceuticals Inc. (NASDAQ:VNDA) today announced positive results from the SET (Safety and Efficacy of Tasimelteon) Phase III study, evaluating tasimelteon, a circadian regulator for the treatment of Non-24-Hour Disorder (Non-24). Tasimelteon succeeded in the primary endpoint of Entrainment of the melatonin (aMT6s) rhythm as compared to placebo.

Additionally, tasimelteon demonstrated significant improvements across a number of sleep and wake parameters including measures of total sleep time, nap duration, and timing of sleep. Tasimelteon also showed significant improvements over placebo in the Non-24 Clinical Response Scale (N24CRS) as well as in the Clinical Global Impression of Change (CGI-C), an overall global functioning scale. These results provide robust evidence of a direct and clinically meaningful benefit to patients with Non-24.

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.

“Today’s results confirm tasimelteon as a strong circadian regulator capable of entraining the master body clock in patients with Non-24. We are particularly impressed and excited by the magnitude and robustness of the direct clinical benefits to patients,” said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. “We believe that tasimelteon can be an effective and clinically meaningful treatment for patients suffering with this debilitating disorder.”

“As a person who regularly experiences the debilitating symptoms of Non-24, these findings are important to me and I think they are important to the blind community as a whole, because they give us hope that a potential new treatment approach is on the horizon,” said Melanie Brunson, Executive Director of the American Council of the Blind.

Primary Endpoints

The SET study was an 84 patient randomized, double-masked, placebo-controlled study in patients with Non-24. The primary endpoints for this study were Entrainment of the melatonin (aMT6s) rhythm to the 24-hour clock and Clinical Response as measured by Entrainment plus a score of $^{3}3$ on N24CRS.

Primary Endpoint Results

Table 1

	Tasimelteon (%)	Placebo (%)	p-value
Entrainment (aMT6s)	20.0	2.6	0.0171
Clinical Response (Entrainment[1]+ N24CRS[3]3)	23.7	0.0	0.0028
Clinical Response[2] (Entrainment[1]+ N24CRS[3]2)	28.9	0.0	0.0006
N24CRS[3]3[2]	28.9	2.9	0.0031
N24CRS[3]2[2]	57.9	20.6	0.0014

1) Entrainment status from the randomized portion of the SET study and/or the screening portion of the RESET study
2) Sensitivity Analysis

Secondary Endpoints

The SET study also assessed a number of secondary endpoints including Entrainment of cortisol rhythm and a broad range of clinical sleep and wake parameters. These parameters included improvement in the total nighttime sleep in the worst 25% of nights (LQ-nTST), decrease in the total daytime sleep duration in the worst 25% of days (UQ-dTSD) and midpoint of sleep timing (MoST) which is derived from a combination of the sleep reported for both nighttime and daytime. CGI-C is a seven-point rating scale of global functioning with lower scores indicating larger improvements.

Secondary Endpoint Results

Table 2

	Tasimelteon	Placebo	p-value
Entrainment (cortisol) (%)	17.5	2.6	0.0313
N24CRS (LS mean)	1.77	0.67	0.0004
CGI-C[1] (LS mean)	2.6	3.4	0.0093
LQ-nTST and UQ-dTSD [3] 90 min[2] (%)	23.8	4.5	0.0767
LQ-nTST and UQ-dTSD [3] 45 min[3] (%)	31.6	8.8	0.0177
LQ-nTST (LS mean minutes)	57.0	16.8	0.0055
UQ-dTSD[1] (LS mean minutes)	-46.2	-18.0	0.0050
MoST (LS mean minutes)	34.8	14.4	0.0123

1) For CGI-C and UQ-dTSD smaller numbers indicate improvement.
2) For this endpoint, only subjects with significant sleep and nap problems at baseline were included.
3) Sensitivity Analysis

The results of the SET study represent the initial data from the tasimelteon Non-24 Phase III development program and demonstrate the multiple benefits of this novel therapy in treating patients suffering from this rare circadian rhythm disorder. In the SET study, tasimelteon was demonstrated to be safe and well tolerated. Vanda expects to report top-line results from the second Phase III study (RESET) for tasimelteon in Non-24 in the first quarter of 2013. Vanda plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in mid-2013.

“We would like to thank our patients, their advocates, investigators, advisors and colleagues for making this study possible,” said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. “We look forward to the successful completion of the Non-24 clinical program.”

Non-24 Scale of Clinical Response (N24CRS)

Assessment	Threshold of response
LQ-nTST	³45 minutes increase in average nighttime sleep duration
UQ-dTSD	³45 minutes decrease in average daytime sleep duration
MoST	³30 minutes increase and a standard deviation £2 hours during double-masked phase
CGI-C	£2.0 from the average of Day 112 and Day 183 compared to baseline

Tasimelteon Development Program for Non-24

The SET study is the first of four clinical studies conducted as part of Vanda’s Phase III development program for tasimelteon in the treatment of Non-24. Data from the RESET study, a Phase III study evaluating the maintenance of entrainment effect of tasimelteon, is expected in the first quarter of 2013. In addition, two safety studies are ongoing to support an NDA filing in the U.S. The tasimelteon Non-24 development program is the largest conducted to date for any investigational therapy for the treatment of 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 in 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. Non-24 sufferers 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. The sleep condition 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://24sleepwake.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_1 and MT_2 receptors, with a 2-4 times 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 development for both Non-24 and Major Depressive Disorder (MDD).

Conference Call

Vanda has scheduled a conference call for today, Tuesday, December 18, 2012 at 9 AM ET to discuss the trial results. Investors can call 1-800-901-5231 (domestic) and 1-617-786-2961 (international) and use passcode 51793839. A replay of the call will be available beginning Tuesday, December 18, 2012, at 11:00 AM ET and will be accessible until Tuesday, December 25, 2012, at 12:00 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 17591426.

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 January 17, 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:

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

Media Contact:

Kristie Kuhl
Senior Vice President
Makovsky & Company, Inc.
(212)-508-9642
kkuhl@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; the failure of Vanda’s clinical trials to demonstrate the safety and/or efficacy of tasimelteon in the treatment of Non-24-Hour Disorder or Major Depressive 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; delays in the completion of Vanda’s RESET clinical trial for tasimelteon; 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. 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.