
**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): October 15, 2012

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 20037

(Address of principal executive offices and zip code)

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

Not Applicable

(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 7.01. Regulation FD Disclosure

On October 15, 2012, Vanda Pharmaceuticals Inc. (the “Company”) issued a press release providing an update regarding its clinical development program for tasimelteon in the treatment of Non-24-Hour Disorder in totally blind individuals with no light perception. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Form 8-K and the press release furnished as Exhibit 99.1 to this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release of Vanda Pharmaceuticals Inc. dated October 15, 2012. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 Kelly

Name: James Kelly

Title: Chief Financial Officer

Dated: October 15, 2012

Tasimelteon Restores Daily Cortisol Rhythms in Blind Patients with Non-24-Hour Disorder

WASHINGTON, D.C. October 15 2012, /PRNewswire/— Vanda Pharmaceuticals (NASDAQ:VNDA), a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders, reported today that tasimelteon has been shown for the first time to restore daily cortisol rhythms in totally blind patients suffering from Non-24-Hour Disorder (Non-24). Tasimelteon was previously reported to entrain the 24-hour rhythm of melatonin secretion in patients with Non-24. Cortisol is a key regulatory hormone which exhibits a circadian rhythm, rising in the early morning and falling in the evening. The circadian regulation of the cortisol rhythm is necessary for the human body to be prepared for a wide range of daily activities and physiologic functions, including blood pressure variation, utilization of fatty acids, circulating lymphocytes and immunity. A growing body of data suggests that tasimelteon's entraining effects are accomplished through a direct resetting of the master body clock, located in the suprachiasmatic nucleus (SCN) of the hypothalamus. Tasimelteon is a circadian regulator in development for the treatment of Non-24 in totally blind individuals.

"It is particularly noteworthy that tasimelteon can entrain the diurnal cortisol rhythm," said Dr. Fred Turek, Director of the Center for Sleep & Circadian Biology at Northwestern University, "because it is an endocrine rhythm that is tightly regulated by the master clock in the SCN, indicating that tasimelteon is acting on the central circadian clock in humans."

"We have confirmed that the circadian dyssynchrony seen in Non-24 extends beyond the melatonin rhythm and the sleep-wake cycle and into the dyssynchrony of the fundamental diurnal variation of endocrine system function as exemplified by the circadian rhythm of cortisol," said Mihael H. Polymeropoulos, MD, President and CEO of Vanda. "Tasimelteon's effect on both melatonin and cortisol rhythms further confirms its potential to reset the master body clock and address the circadian dyssynchrony which is inherent in Non-24."

This observation was made during an open-label segment of Vanda's RESET study. RESET is a Phase III study of the maintenance effect of tasimelteon in the treatment of Non-24. Totally blind patients with Non-24 were given a 20mg dose of tasimelteon daily at bed time for 6 weeks. The rhythms of melatonin and cortisol were assessed longitudinally in urine samples. Entrainment of the cortisol rhythm by tasimelteon was directly associated with entrainment of the melatonin rhythm in the same patients. Vanda believes that the simultaneous entrainment of both melatonin and cortisol suggests that tasimelteon can reset the master body clock in the SCN through binding to MT1 and MT2 melatonin receptors. Tasimelteon's unique balanced melatonin receptor binding profile may make it well-suited to perform as a circadian regulator.

The master body clock controls the timing of many aspects of physiology, behavior and metabolism that show daily rhythms, including the sleep-wake cycles, body temperature, alertness and performance, metabolic rhythms and certain hormones which exhibit circadian variation. Outputs from the SCN control many endocrine rhythms including those of melatonin secretion by the pineal gland as well as the control of cortisol secretion via effects on the hypothalamus, the pituitary and the adrenal glands.

This master body clock, located in the SCN, spontaneously generates rhythms of approximately 24.5 hours. These non-24-hour rhythms are synchronized each day to the 24-hour day-night cycle by light, the primary environmental time cue which is detected by specialized cells in the retina and transmitted to the SCN via the retino-hypothalamic tract. Inability to detect this light signal, as occurs in most totally blind individuals, leads to the inability of the master body clock to be reset daily and maintain entrainment to a 24-hour day. This newly reported observation of tasimelteon's ability to restore cortisol rhythms in patients with Non-24 opens new avenues of inquiry and discovery in the field of circadian rhythm disorders.

References

Cui, He, Akira Kohsaka, Hidefumi Waki, Mohammad E. R. Bhuiyan, Sabine S. Gouraud, and Masanobu Maeda. "Metabolic Cycles Are Linked to the Cardiovascular Diurnal Rhythm in Rats with Essential Hypertension." *PLoS ONE* E17339 6.2 (2011): 1-13.

Fu, Loning, and Cheng C. Lee. "The Circadian Clock: Pacemaker and Tumour Suppressor." *Nature Reviews* 3 (2003): 350-61.

Young, M., and M. Bray. "Potential Role for Peripheral Circadian Clock Dyssynchrony in the Pathogenesis of Cardiovascular Dysfunction." *Sleep Medicine* 8.6 (2007): 656-67.

About Non-24-Hour Disorder

Non-24-Hour Disorder is a chronic circadian rhythm disorder that affects more than 50 percent of the totally blind individuals in the U.S., or 65,000 to 95,000 people. Non-24 occurs almost entirely in individuals who are totally blind and lack the light sensitivity necessary to reset the circadian clock. Without light perception, the brain's circadian rhythms which guide many of the body's functions, including sleep, hormone rhythms and metabolism are not reset to a regular 24-hour cycle.

Individuals with Non-24 are unable to synchronize their internal clock to the 24-hour day-night cycle, which disrupts their sleep-wake cycle. For more information, please visit <http://24sleepwake.com/>.

About Tasimelteon

Tasimelteon, an MT1 and MT2 agonist is currently being tested in two Phase III efficacy studies (SET and RESET) for the treatment of Non-24 in totally blind patients. Vanda expects to report top-line results from the SET study by year end 2012. Top-line results from the RESET study are expected in the first quarter of 2013. These studies will inform a New Drug Application (NDA) with the US Food and Drug Administration (FDA), which is expected to be submitted in mid-2013.

Tasimelteon is being studied in both Non-24 and Major Depressive Disorder (MDD).

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 Pharmaceuticals Inc., please visit <http://www.vandapharma.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 extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda’s ability to successfully commercialize Fanapt® outside of the U.S. and Canada; delays in the completion of Vanda’s clinical trials; a failure of Vanda’s products, product candidates or partnered products to be demonstrably safe and effective; Vanda’s failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda’s products, product candidates or partnered products in the marketplace, or a failure to become or remain profitable; Vanda’s expectations regarding trends with respect to its costs and expenses; Vanda’s inability to obtain the capital necessary to fund additional research and development activities; Vanda’s failure to identify or obtain rights to new products or product candidates; Vanda’s failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda’s ability to utilize some or all of its prior net operating losses and research and development credits; a loss of any of Vanda’s key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda’s products or product candidates under its license and sublicense agreements 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.

Investor/Media Contact:

Cristina Murphy
Senior Communications Manager
Vanda Pharmaceuticals Inc.
(202) 734-3400
cristina.murphy@vandapharma.com