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 10, 2018

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 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On December 10, 2018, Vanda Pharmaceuticals Inc. issued a press release announcing results from the VEC-162-2401 clinical study of HETLIOZ® in Smith-Magenis Syndrome. 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 10, 2018.

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.

Dated: December 10, 2018

By: /s/ Timothy Williams
Name: Timothy Williams
Title: Senior Vice President, General Counsel and Secretary

Exhibit 99.1

Vanda Announces Positive Pivotal Study Results for HETLIOZ® (tasimelteon) in Patients with Smith-Magenis Syndrome

WASHINGTON, December 10, 2018 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that HETLIOZ® (tasimelteon) improved sleep quality and increased sleep duration in patients with Smith-Magenis Syndrome (SMS) in a pivotal placebo controlled clinical study.

“We are extremely pleased with the results of this study of tasimelteon in patients with Smith-Magenis Syndrome. Tasimelteon was shown to meaningfully improve sleep in SMS patients, addressing an unmet medical need for the most severe symptom constellation of this rare disorder,” said Mihael H. Polymeropoulos MD, Vanda’s President and Chief Executive Officer.

VEC-162-2401 was a double masked 4 week cross-over pivotal clinical trial that studied the effects of tasimelteon versus placebo in 25 patients with SMS. Patients were evaluated for daily diary sleep quality (DDSQ) and for daily diary total nighttime sleep duration (DDTST) via a parental post sleep questionnaire (PSQ). Total nighttime sleep duration was also measured via daily actigraphy. The study had two predefined primary endpoints: DDSQ and DDTST.

Tasimelteon met the primary endpoint of improvement in the 50% worst sleep quality (DDSQ) (p=0.0139) and also showed improvement on the primary endpoint of 50% worst total nighttime sleep duration (DDTST) (p=0.0556) (Table 1).

Tasimelteon demonstrated significant improvement in overall sleep quality (DDSQ) (p=0.0155) and overall total nighttime sleep duration (DDTST) (p=0.0134). Tasimelteon improved the overall total nighttime sleep duration (DDTST) by an average of approximately 41 minutes per night, a highly clinically meaningful effect. Given that most of the baseline nights were of shortened sleep duration, tasimelteon also improved sleep duration for the best half of the baseline nights versus placebo (50% best DDTST, 46.6 min, p=0.0052). Tasimelteon also showed significant improvement in subjective measures of total nighttime sleep duration via actigraphy, for 50% worst TST (p=0.0309) and overall TST (p=0.0218) (Table 1).

In this study, aberrant behaviors improved from baseline on both tasimelteon and placebo but likely due to the relative short duration of the study the differences were not significant between the two groups. In a longer open label study of tasimelteon in SMS, patients were treated for a period of approximately 27 weeks following a 6 week baseline evaluation. In that study, significant improvements from baseline were observed in sleep quality (DDSQ, p=0.0105) as well as in aberrant behaviors (Aberrant Behavior Checklist, p=0.0006)[1].

The improvements in sleep quality and sleep duration demonstrated in the 2401 study were consistent across patients with chromosomal deletions of various lengths as well as a single patient with a point mutation in the RAI1 gene on chromosome 17p. The detailed results are expected to be presented in upcoming meetings and peer reviewed publications.

“Individuals with Smith-Magenis syndrome have significantly impaired sleep with altered sleep-wake cycles. This chronic sleep deprivation impacts cognitive and behavioral function on a daily basis. The sleep disturbance that occurs in this disorder impacts the entire family. The improved sleep duration and sleep quality with tasimelteon as shown in this study can provide a significant improvement to quality of life for individuals and families affected by this complex genetic condition” said Dr. Sarah Elsea, Professor, Baylor College of Medicine and Chair, PRISMS Professional Advisory Board.

Vanda wants to extend its appreciation to all who worked tirelessly on this multi-year project and especially the patients, their families, their advocates and the PRISMS organization.

VEC-162-2401 is the largest placebo controlled study ever conducted demonstrating significant sleep improvements in patients with SMS. The U.S. Food and Drug Administration has granted orphan drug designation for tasimelteon for the treatment of SMS. Vanda intends to meet with regulatory authorities and seek marketing authorization for the treatment of SMS patients with tasimelteon.

Table 1. Study VEC-162-2401 Results Summary*

Endpoints	Description	Tasimelteon (n=25)	Placebo (n=25)	Difference p-value
Subjective				
Sleep Quality	DDSQ Worst 50%*	0.67	0.27	0.0139
(Scale 1-5)	DDSQ Overall	0.55	0.22	0.0155
Sleep Duration	DDTST Worst 50%*	36.1	17.6	0.0556
(minutes)	DDTST Best 50%	46.6	23.4	0.0052
	DDTST Overall	40.9	19.8	0.0134
Objective				
Sleep Duration	Actigraphy TST Worst 50%	22.3	2.4	0.0309
(minutes)	Actigraphy TST Overall	20.1	1.9	0.0218

* Primary endpoint

For DDSQ, DDTST, Actigraphy TST, the values shown are changes from baseline.

HETLIOZ® is currently approved for the treatment of Non-24 Hour Sleep Wake Disorder. For a review of the current prescribing information of HETLIOZ® please visit www.hetlioz.com.

HETLIOZ® IS NOT CURRENTLY APPROVED BY ANY REGULATORY AUTHORITY FOR THE TREATMENT OF SMS.

Conference Call

The Vanda management team will host a conference call and live webcast today, Monday, December 10, 2018, at 8:30 AM ET to discuss these updates. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 47969899. A replay of the call will be available on Monday, December 10, 2018, beginning at 11:00 AM ET and will be accessible until Monday, December 17, 2018, 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 passcode number is 47969899.

The conference call will be broadcast simultaneously on Vanda's website. 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 or presentations. The call will also be archived on Vanda's website for a period of 30 days.

About Smith-Magenis Syndrome

Smith-Magenis Syndrome (SMS) is a developmental disorder that is caused by a small deletion of human chromosome 17p [2,3]. In more rare cases SMS is caused by a point mutation in the RAI1 gene which resides in the deleted region. SMS is estimated to affect 1/15,000-25,000 individuals. SMS is usually not inherited but rather is due to a de-novo deletion. Patients with SMS present with a number of physical, mental and behavioral problems. The most common symptom of SMS is a severe sleep disorder associated with significant disruption in the lives of patients and their families.

About HETLIOZ® (tasimelteon)

HETLIOZ® (tasimelteon) is a melatonin receptor agonist. HETLIOZ® has been granted market authorization by the U.S. Food and Drug Administration and the European Medicines Agency. For full U.S. prescribing information, please visit www.hetlioz.com.

Important Safety Information

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ® (tasimelteon) than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, and upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ® is increased by approximately 2-fold compared with younger patients.

Indication

HETLIOZ® is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

Important Safety Information

HETLIOZ® may cause somnolence: After taking HETLIOZ®, patients should limit their activity to preparing for going to bed, because HETLIOZ® can potentially impair the performance of activities requiring complete mental alertness.

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ® than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, and upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ® is increased by approximately 2-fold compared with younger patients.

Use of HETLIOZ® should be avoided in combination with fluvoxamine or other strong CYP1A2 inhibitors, because of a potentially large increase in exposure of HETLIOZ®, and a greater risk of adverse reactions. HETLIOZ® should be avoided in combination with rifampin or other CYP3A4 inducers, because of a potentially large decrease in exposure of HETLIOZ®, with reduced efficacy.

There are no adequate and well-controlled studies of HETLIOZ® in pregnant women. Based on animal data, HETLIOZ® may cause fetal harm. HETLIOZ® should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZ® is administered to a nursing woman.

HETLIOZ® has not been studied in patients with severe hepatic impairment and is not recommended in these patients.

Safety and effectiveness of HETLIOZ® in pediatric patients have not been established.

About Vanda

Vanda is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

Abbreviations

SMS	Smith-Magenis Syndrome
TST	Total Sleep Time
SQ	Sleep Quality
DDTST	Daily Diary Total Sleep Time
DDSQ	Daily Diary Sleep Quality

References

1. Hull, J.T., Polymeropoulos, C.M., Cho, Y., Xiao, C., Polymeropoulos, M.H (2017, October 7-11). Tasimelteon Improves Sleep Quality and Behavior in Individuals With Smith Magenis Syndrome (SMS) in an Open-Label Study. Poster Presentation at World Sleep Society (14th world sleep congress). Prague, Czech Republic
2. Williams, S. R., Zies, D., Mullegama, S. V, Grotewiel, M. S., & Elsea, S. H. (2012). Smith-Magenis syndrome results in disruption of CLOCK gene transcription and reveals an integral role for RAI1 in the maintenance of circadian rhythmicity. *Am.J Hum.Genet.*, *90*(1537–6605), 941–949.
3. Gropman, A. L., Duncan, W. C., & Smith, A. C. (2006). Neurologic and developmental features of the Smith-Magenis syndrome (del 17p11.2). *Pediatr.Neurol.*, *34*(0887–8994), 337–350.

FORWARD LOOKING STATEMENTS

Various statements in this release are "forward-looking statements" under the securities laws. 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 Vanda's forward-looking statements include tasimeltion's potential to be approved by regulatory authorities and become a pharmacological option in the treatment of sleep disruptions in patients with SMS; 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, 2017 and quarterly report on Form 10-Q for the quarter ended September 30, 2018, which are on file with the Securities and Exchange Commission (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.

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SOURCE Vanda Pharmaceuticals Inc.