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): July 16, 2019

VANDA PHARMACEUTICALS INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-34186	**03-0491827**
(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 (see General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001	**VNDA**	**The Nasdaq Stock Market LLC (The Nasdaq Global Market)**

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 July 16, 2019, Vanda Pharmaceuticals Inc. issued a press release announcing results from the Motion Sifnos Phase II clinical study of tradipitant in motion sickness. 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 July 16, 2019.

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.

Dated: July 16, 2019

VANDA PHARMACEUTICALS INC.

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

Exhibit 99.1

Tradipitant Effective in Preventing Motion Sickness

Washington, July 16, 2019 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that tradipitant, a neurokinin-1 receptor antagonist, was effective in treating motion sickness in a clinical study conducted in the Pacific Ocean.

The clinical efficacy results reported today are from the Motion Sifnos Phase II clinical study. In this study, 126 people with a prior history of motion sickness were subjected to sea travel in the Pacific Ocean. Study participants were randomized to receive either tradipitant or placebo in a blinded fashion.

The study had two primary endpoints: percentage of participants vomiting, and Motion Sickness Severity Scale (MSSS) Worst score.

In the overall population, a significantly higher percentage of participants experienced vomiting in the placebo arm as compared to the tradipitant arm, 39.7% versus 17.5% respectively, p value = 0.0039. The MSSS Worst score endpoint also favored tradipitant, but the difference did not reach statistical significance, 3.75 versus 3.4, p value = 0.293 (Table 1).

An exploratory analysis was also performed to evaluate the effects of tradipitant under “calm” and “rough” seas. Under “calm” sea conditions, only a small percentage of participants in either arm experienced vomiting, 26.7% versus 18.2% for placebo and tradipitant respectively (not significant). A similar MSSS Worst score was seen between the two groups, 3.32 and 3.40, for placebo and tradipitant respectively (not significant).

Under “rough” sea conditions, 72.2% of the placebo treated patients vomited as compared to 15.8% of those treated with tradipitant, p value = 0.0009. A significant effect was also seen under “rough” conditions in the MSSS Worst score, 4.57 and 3.19 for placebo and tradipitant respectively, p value = 0.0235 (Table 1).

Vanda intends to initiate a Phase III program in Motion Sickness, with a plan to file for marketing authorization in 2020.

Table 1: Results of Motion Sifnos study for the Overall population and for the Calm and Rough Sea sub-populations.

		Tradipitant	Placebo	Difference	P-value
	ITT*	n=63	n=63		
% Vomiting		17.5%	39.7%	22.2%	0.0039
Worst MSSS		3.40	3.75	0.35	0.2936
	Calm Sea	n=44	n=45		
% Vomiting		18.2%	26.7%	8.5%	0.3123
Worst MSSS		3.4	3.32	-0.09	0.8271
	Rough Sea	n=19	n=18		
% Vomiting		15.8%	72.2%	56.4%	0.0009
Worst MSSS		3.19	4.57	1.38	0.0235

* ITT = Intent To Treat

Motion Sickness

Motion Sickness is a disorder that arises often as a response to real or perceived movement, as occurring during vehicular travel. Vomiting is the most disturbing symptom of motion sickness, although the disorder is often accompanied by a constellation of symptoms that includes nausea, sweating, pallor, headache and anorexia[1].

It is believed that a discrepancy between actual body position and perceived body position triggers the maladaptive response of motion sickness[2]. It is reported that approximately 30% of the general population suffers from Motion Sickness under ordinary travel conditions that include sea, air and land travel[3].

Despite the increasing prevalence of the disorder, the treatments available today, antihistamines and anticholinergics, were first discovered in the 1940's and found utility in transporting US troops across the Atlantic Ocean in the post World War II era.

According to IQVIA data, approximately two to three million doses of Dramamine, a common motion sickness remedy, are purchased monthly in the US. Dramamine treated patients represent only a fraction of the people treated monthly for motion sickness.

Motion sickness is one of the most prevalent episodic disorders in the world, whose prevalence has dramatically increased with world population mobility over the last 100 years.

The US Transportation Department, Bureau of Transportation Statistics, reports 10 billion trips per year in mass transit (buses and trains), with an additional 965 million passenger trips in domestic and international air travel[4].

Motion Sifnos clinical study

The Motion Sifnos study was a proof of concept Phase II clinical study. During this randomized double blind placebo controlled study, 126 people with prior history of motion sickness were exposed to sea travel in the Pacific Ocean under varied weather conditions.

Study participants were distributed over seven boat trips that took place between January and May of 2019 off the coast of Los Angeles. Sea conditions were recorded for each trip, as was participant evaluation of the symptoms of motion sickness. For three of the seven trips, sea conditions were “rough”, conducive to producing motion sickness with wave heights above 1 meter. For the remaining four trips, conditions were “calm”, with wave heights less than 1 meter and, therefore, less likely to produce motion sickness. Under “rough” sea conditions, 72.2% of the placebo treated patients experienced vomiting compared to only 26.7% under “calm” conditions.

Study participants were randomized to receive tradipitant 170 mg or placebo by mouth in a blinded fashion, prior to travel initiation, and reported their symptoms at predetermined time intervals during the travel period. The study had two primary endpoints: Percentage of participants vomiting and MSSS Worst score. The MSSS is a 7 point scale ranging from 0 “no symptoms” to 6 “vomiting”.

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.

References

1. Simon RP, Aminoff MJ, Greenberg DA. Clinical Neurology. 2017. New York, New York: McGraw-Hill.

2. Reason JT. Motion sickness adaptation: a neural mismatch model. Journal of the Royal Society of Medicine. 1988: 71: 819-829.

3. Turner M, Griffin MJ. Motion sickness in public road transport: passenger behavior and susceptibility. Egonomics. 1999: 42: 444-461.

4. US Department of Transportation, Office of the Secretary of Transportation, Bureau of Transportation Statistics. 2018 Transportation Statistics Annual Report.

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 tradipitant’s potential to be approved by regulatory authorities and become an approved treatment for motion sickness 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, 2018 and quarterly report on Form 10-Q for the quarter ended March 31, 2019, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC’s website at www.sec.gov. Additional factors may be set forth in those sections of Vanda’s quarterly report on Form 10-Q for the quarter ended June 30, 2019, to be filed in the third quarter of 2019. 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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