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 3, 2018

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:

☐ 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 3, 2018, Vanda Pharmaceuticals Inc. issued a press release announcing results from VLY686-2301, a phase II clinical study of tradipitant in patients with idiopathic and diabetic gastroparesis. 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 3, 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 3, 2018	By: /s/ Timothy Williams
	Name: Timothy Williams
	Title: Senior Vice President, General Counsel and Secretary

Exhibit 99.1

Vanda Announces Positive Phase II Study Results for Tradipitant in Patients with Gastroparesis

Management to host conference call on Monday, December 3 at 8:30 AM ET

Washington, December 3, 2018 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq:VNDA) today announced that tradipitant met the primary endpoint in VLY686-2301, a Phase II clinical study in patients with idiopathic and diabetic gastroparesis. The study also showed that tradipitant was well tolerated with comparable rates of adverse events between the tradipitant and placebo groups.

"The results of the VLY686-2301 study pave the way for further development of tradipitant as potentially the first new drug for gastroparesis in almost 40 years. The highly clinically meaningful and significant improvements observed in the primary endpoint of nausea, the significant increase in nausea free days, and the reported overall symptom improvement, suggest a potential breakthrough discovery in the treatment of the millions of people estimated to have gastroparesis" said Mihael H. Polymeropoulos MD, Vanda's President and Chief Executive Officer.

VLY-686-2301 was a Phase II clinical trial that studied the effects of tradipitant (85 mg twice a day) versus placebo in 141 patients in an Intent To Treat (ITT) population with gastroparesis over a period of 4 weeks. Several symptom severity scales were used to assess gastroparesis symptoms, including the Gastroparesis Symptom Index (GCSI), Patients Assessment of Upper Gastrointestinal Disorders–Symptoms (PAGI-SYM), and Patient Global Impression of Change (PGI-C) as well as a Clinician Global Impression of Severity (CGI-S).

Tradipitant met the primary endpoint of the study of change in nausea score as measured by patient daily diaries (change of -1.2 for tradipitant versus -0.7 for placebo, p=0.0099) and also met the related endpoint of improvement in the number of nausea free days (an addition of 28.8% of days for tradipitant versus 15.0% for placebo, p=0.0160). Tradipitant also showed significant improvement in most of the secondary endpoints studied, including the several key scales reflecting overall gastroparesis symptoms; GCSI (p=0.0223); PAGI-SYM (p=0.0497); CGI-S (p=0.0207); PGI-C (p=0.0429). See Table 1.

In a subgroup analysis of patients that experienced both nausea and vomiting at baseline (n=101), tradipitant showed highly significant effects on the primary endpoint of change in nausea score (change of -1.4 for tradipitant versus -0.4 for placebo, p=0.00002) as well as the number of nausea free days (an addition of 32.3% for tradipitant versus 7.6% for placebo, p=0.0003).

Importantly, improvements were also seen in most of the core gastroparesis symptoms including nausea, vomiting, bloating, and fullness after meals consistent with an overall improvement and no associated worsening of any of the core symptoms. Most effects were apparent by the second week of treatment although improvements continued through the fourth and last week of treatment in the tradipitant group. Adverse events were similar in the tradipitant and placebo arms which confirms prior studies' findings that tradipitant is well tolerated.

Vanda believes that if these robust efficacy results with a well-tolerated chronic treatment safety profile are further confirmed in future studies, tradipitant has the potential to become a first line pharmacological option in the treatment of patients with gastroparesis. The detailed results of this study are expected to be presented in upcoming meetings and peer reviewed publications.

In addition, Vanda expects to meet with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis.

Table 1. Study VLY-686-2301 Results Summary*

ITT Population (n=141)

	Tradipitant n=73	Placebo n=68	p-value
Primary End Point			
DD-Nausea	-1.25	-0.73	0.0099
Secondary End Points			
DD-% Nausea Free Days	28.8	15.0	0.0160
GCSI	-0.93	-0.58	0.0223
PAGI-SYM	-0.93	-0.65	0.0497
CGI-S	-1.13	-0.74	0.0207
PGI-C	2.66	3.06	0.0429

Vomiting Population (n=101)

	Tradipitant n=58	Placebo n=43	p-value
Primary End Point:			
DD-Nausea	-1.43	-0.42	<0.0001
Secondary End Points:			
DD-% Nausea Free Days	32.3	7.6	0.0003
GCSI	-1.10	-0.60	0.0078
PAGI-SYM	-1.06	-0.69	0.0294
CGI-S	-1.24	-0.79	0.0229
PGI-C	2.52	3.24	0.0018

* For DD-Nausea, DD-% Nausea Free Days, GCSI, PAGI-SYM and CGI-S, the values shown are changes from baseline.

Conference Call

The Vanda management team will host a conference call and live webcast today, Monday, December 3, 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 3, 2018, beginning at 11:00 AM ET and will be accessible until Monday, December 10, 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 Gastroparesis

Gastroparesis is a serious medical condition characterized by delayed gastric emptying associated with the symptoms of nausea, vomiting, bloating, fullness after meals and abdominal pain, along with significant impairment of social and occupational functioning. The estimated prevalence of gastroparesis in the U.S. is over 5 million patients many of whom remain undiagnosed.[2] Gastroparesis affects mostly women and it can be of diabetic, idiopathic or other etiology. The only U.S. Food and Drug Administration approved treatment for gastroparesis is metoclopramide, approved in 1979, which due to its potential of severe side effects carries a black box warning and limitations of use of no more than 3 months. Patients are faced with limited therapeutic options and clinical guidelines recommend, in addition to metoclopramide, the off label use of different drugs including erythromycin, domperidone (not approved in the U.S.), botulinum toxin injections, gastric stimulators and a variety of surgical procedures in an effort to relieve even temporarily some of the symptoms of the disease[3]. Gastroparesis treatment represents a significant unmet medical need as underscored by the testimonies of interested parties and advocacy organizations including the International Foundation for Gastrointestinal Disorders (IFFGD) and Gastroparesis Patient Association for Cures and Treatments, Inc. (G-Pact).

The precise underlying mechanisms leading to gastroparesis are currently poorly understood and are believed to be diverse in nature. The consensus suggests that gastroparesis arises from a dysregulation of the neuromuscular control of gastric movements that result in the timely emptying of stomach contents. The two key stimulatory neurotransmitters of the digestive system are acetylcholine and the neuropeptide substance P. Substance P acts by binding the neurokinin 1 receptor (NK-1R) at the gastric neuromuscular junction and it is believed that there is a functional interplay between the acetylcholine and NK-1R systems. Moreover gastroparesis symptoms are also associated with aberrant physiology of the vagus nerve which constitutes the major connection between the stomach and the central nervous system.[1] Vanda believes that blockade of the NK-1Rs may have a dual and potentially therapeutic effect in gastroparesis by affecting gastric motility through a local action as well as affecting nausea and vomiting via a direct effect in the brain regions responsible for nausea and vomiting.

About Tradipitant

Tradipitant is an NK-1R antagonist licensed by Vanda from Eli Lilly and Company in April 2012. Tradipitant is currently in clinical development for gastroparesis as well as in Phase III for atopic dermatitis. The patent describing tradipitant as a new chemical entity is expected to expire in the United States in June 2029 based on an anticipated Hatch-Waxman patent term extension.

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

DD-Nausea: Daily Diary Nausea score (0-5)
DD-% Nausea Free Days: Daily Diary Nausea Free Days percent (0-100)
ITT: Intent To Treat
GCSI: Gastroparesis Cardinal Symptom Index
PAGI-SYM: Patient Assessment of Gastrointestinal Disorders – Symptoms
CGI-S: Clinician Global Impression of Severity
PGI-C: Patient Global Impression of Change

References

1. Almeida TA, Rojo J, Nieto PM, Pinto FM, Hernandez M, et al. Tachykinins and tachykinin receptors: structure and activity relationships. Current Medicinal Chemistry. 2004;11:2045-2081.
2. Rey E., Choung RS, Schleck CD, Zinsmeister AR, Talley NJ, Locke GR 3rd. Prevalence of hidden gastroparesis in the community: the gastroparesis "iceberg." *J Neurogastroenterol Motil.* Vol. 18 No. 1 (2012).
3. Camilleri, M., Chedid, V., Ford, A.C., Haruma, K., Horowitz, M., Jones, K.L., Low, P.A., Park, S., Parkman, H.P. and Stanghellini V. Gastroparesis. *Nature Reviews Disease Primers.* 4:14 (2018).

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, among others: the ability of NK-1R inhibition to provide significant benefit in the treatment of gastroparesis and chronic pruritus in patients with atopic dermatitis; the results of Vanda's clinical development activities for tradipitant; delays in the completion of Vanda's clinical development of tradipitant; a failure of tradipitant to be demonstrably safe and effective; tradipitant's potential to become a first line pharmacological option in the treatment of patients with gastroparesis; 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.