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): February 4, 2022

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 (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 per share	**VNDA**	**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 February 4, 2022, Vanda Pharmaceuticals Inc. issued a press release regarding the results from the Phase III clinical study of tradipitant in gastroparesis. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is 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 February 4, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: February 4, 2022

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Reports Results from the Phase III Study of Tradipitant in Gastroparesis

February 4, 2022

WASHINGTON, February 4, 2022 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced results from its Phase III clinical study, VP-VLY-686-3303, evaluating the efficacy and safety of tradipitant in treating the symptoms of gastroparesis. The study did not meet its prespecified primary endpoint which was the difference between drug and placebo on the change of the severity of nausea from baseline at week 12 of treatment. Both treatment arms showed significant improvements from baseline on nausea as well as the other core symptoms of gastroparesis.

Initial exploratory analysis has identified potential confounders that may have masked the beneficial effect of the drug previously observed in the Phase II study of tradipitant, which include a baseline imbalance of rescue medication use between the two treatment arms as well as an observed poor compliance with study drug for some patients in the study. When restricting the analysis in the group of patients that used no rescue medications at baseline and adjusting for poor compliance, Vanda identified strong evidence of a drug effect across a number of symptoms and across the duration of the study, including a significant and meaningful effect at the prespecified primary endpoint of nausea change at week 12.

The Phase III study also continued to demonstrate that tradipitant is safe and well-tolerated, as seen in previous studies over the 12 weeks of treatment. Patients on tradipitant experienced a similar number of treatment emergent adverse events as patients receiving placebo. The most common adverse event where tradipitant frequency was higher than placebo was diarrhea. Patients that participated in the clinical program also had the opportunity to seek expanded access to tradipitant based on the benefit in the study and their individual unmet medical needs. Ten patients have received more than 3 months of tradipitant treatment, 6 of whom have received at least 1 year of tradipitant treatment.

“While disappointed that the study did not meet its prespecified outcome, we are encouraged by the evidence that is emerging from further analysis that confirms observations made in the prior clinical study,” said Mihael H. Polymeropoulos, M.D., Vanda’s President, CEO and Chairman of the Board. “We are committed to completing our analysis and working to bring tradipitant to patients with gastroparesis to fill a significant unmet medical need.”

Vanda plans to continue the analysis of the data of this study and prepare the results for submission to peer review journals as well as prepare the data for submission to regulatory authorities.

Conference Call

Vanda intends to schedule a conference call to discuss these results in the coming weeks. Details on timing and instructions to access the call will be publicly announced in advance.

About Tradipitant

Tradipitant is a neurokinin-1 receptor antagonist licensed by Vanda from Eli Lilly and Company. Tradipitant is currently in clinical development for gastroparesis and motion sickness. The FDA has imposed a partial clinical hold on tradipitant clinical protocols of longer than 12 weeks duration.

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 approximately 6 million patients, many of whom remain undiagnosed.[1] 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.[2] 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).

References

1. Rey, E., Choung, R. S., Schleck, C. D., Zinsmeister, A. R., Talley, N. J., & Locke, G. R., 3rd (2012). Prevalence of hidden gastroparesis in the community: the gastroparesis “iceberg”. *Journal of neurogastroenterology and motility*, *18*(1), 34–42. https://doi.org/10.5056/jnm.2012.18.1.34
2. Camilleri, M., Chedid, V., Ford, A. C., Haruma, K., Horowitz, M., Jones, K. L., Low, P. A., Park, S. Y., Parkman, H. P., & Stanghellini, V. (2018). Gastroparesis. *Nature reviews. Disease primers*, *4*(1), 41. https://doi.org/10.1038/s41572-018-0038-z

About Vanda Pharmaceuticals Inc.

Vanda is a leading 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 and follow us on Twitter @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda’s plans for further analysis of study data and publication of study results and Vanda’s continued pursuit of regulatory approval of tradipitant for the treatment of the symptoms of gastroparesis 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, Vanda's ability to complete the clinical development of, submit a new drug application for, and obtain regulatory approval of tradipitant in the treatment of the symptoms of gastroparesis, Vanda's ability to resolve its disagreement with the FDA regarding the conduct of a 9-month non-rodent chronic toxicity study, and the FDA's assessment of the adequacy of Vanda's safety and efficacy data. Therefore, no assurance can be given that the 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. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "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, 2020, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

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 press release is provided only as of the date of this press 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, except as required by law.

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