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): September 19, 2024

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) (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(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VNDA	The Nasdaq Global Market
Series A Junior Preferred Stock Purchase Right, par value $0.001 per share	—	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 September 19, 2024, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release providing an update on the status of Vanda’s tradipitant development program.

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	Vanda Pharmaceuticals Inc. press release dated September 19, 2024
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: September 19, 2024

VANDA PHARMACEUTICALS INC.

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

FDA Declines to Approve Vanda's Marketing Application for Tradipitant in Gastroparesis

WASHINGTON, September 19, 2024 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today provided an update on its tradipitant development program.

On September 18, 2024, the U.S. Food and Drug Administration (FDA) declined to approve Vanda's New Drug Application (NDA) of tradipitant for the treatment of symptoms in gastroparesis, providing Vanda with a Complete Response Letter (CRL).

Gastroparesis is a serious condition that is characterized by delayed gastric emptying and associated with severe nausea, vomiting, difficulty finishing a normal meal and other symptoms that have a significant impact in people's everyday living and functioning. Gastroparesis is often associated with diabetes but is also found in nondiabetic individuals and has recently been associated with the class of GLP1 inhibitors. There has been no effective treatment approved by the FDA in over 40 years.

Vanda's tradipitant application included evidence from two placebo-controlled studies, the results of which were published in peer review journals.[1,2] The evidence of efficacy was further supported by exposure response data from a large open label study as well as the real world experience of dozens of patients treated in an expanded access program, some for several years.

The CRL was conclusory in nature, generally disregarded the evidence provided and instead suggested that Vanda conduct additional studies with a design and duration inconsistent with the advice of key experts in the field and not appropriate based on the scientific understanding and natural course of the disorder.

Furthermore, the FDA's action was delayed by more than 185 days and fails to satisfy the requirements specified by the Food Drug and Cosmetic Act (FDCA). The FDCA requires that the FDA review a new drug application and within 180 days of submission provide either an approval or an opportunity for a hearing. In this case the FDA failed to do either.

Despite this disappointing action by the FDA, Vanda believes that the tradipitant application has met the substantial evidence of efficacy standard with a favorable benefit risk profile for the treatment of patients with gastroparesis. While Vanda has repeatedly requested that the FDA convene an expert advisory committee to review the application and advise the Commissioner on the approvability of this application, the FDA has refused to do so. A number of patients currently treated with tradipitant have filed a Citizen Petition urging FDA to approve tradipitant for the treatment of gastroparesis.

Vanda will continue to pursue the marketing authorization for tradipitant and will continue to support the expanded access program that is currently serving several dozen patients with gastroparesis. Vanda encourages any patients with questions about expanded access to contact us at the following email address ExpandedAccess@vandapharma.com.

Vanda plans to submit a separate NDA for tradipitant for the prevention of vomiting in motion sickness later this year.

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 X @vandapharma.

References

1. Carlin, J. L., Polymeropoulos, C., Camilleri, M., Lembo, A., Fisher, M., Kupersmith, C., Madonick, D., Moszczynski, P., Smieszek, S., Xiao, C., Birznieks, G., & Polymeropoulos, M. H. (2024). The efficacy of tradipitant in patients with diabetic and idiopathic gastroparesis in phase III randomized placebo-controlled clinical trial. *Clinical Gastroenterology and Hepatology*. Available online: https://www.cghjournal.org/article/S1542-3565(24)00050-8/fulltext
2. Carlin, J. L., Lieberman, V. R., Dahal, A., Keefe, M. S., Xiao, C., Birznieks, G., Abell, T. L., Lembo, A., Parkman, H. P., & Polymeropoulos, M. H. (2021). Efficacy and Safety of Tradipitant in Patients With Diabetic and Idiopathic Gastroparesis in a Randomized, Placebo-Controlled Trial. *Gastroenterology*, *160*(1), 76–87.e4. Available online: https://doi.org/10.1053/j.gastro.2020.07.029

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, statements regarding Vanda's plans for pursuit of FDA approval of tradipitant for the treatment of symptoms of gastroparesis and motion sickness are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances 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 and submit to the FDA the NDA for tradipitant for the treatment of motion sickness within the specified timeframe and the FDA's assessment of the sufficiency of the data packages to be included in the NDA for tradipitant. 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 most recent Annual Report on Form 10-K, 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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