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 5, 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 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 5, 2024, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release providing an update on the status of the U.S. Food and Drug Administration’s review of Vanda’s supplemental New Drug Application for HETLIOZ® in the treatment of insomnia.

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 5, 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: February 5, 2024

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Announces FDA Update for supplemental NDA for HETLIOZ® in the Treatment of Insomnia

WASHINGTON, February 5, 2024 /PRNewswire/ — Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that on February 4, 2024, it received a notification from the U.S. Food and Drug Administration (FDA) stating that as part of its ongoing review of Vanda's supplemental New Drug Application (sNDA) for HETLIOZ® (tasimelteon) in the treatment of insomnia characterized by difficulties with sleep initiation, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. No deficiencies were disclosed by the FDA in the notification, and the FDA stated that the notification does not reflect a final decision on the information under review. In a letter to Vanda dated July 17, 2023, the FDA had assigned a Prescription Drug User Fee Act target date of March 4, 2024 for the completion of its review of the sNDA.

Vanda has extensively studied the efficacy of HETLIOZ® in the treatment of insomnia characterized by difficulties with sleep initiation. A Phase III, multi-center, placebo-controlled, 4-week trial evaluated patients with chronic primary insomnia. Two transient insomnia studies induced by phase advance of the sleep-wake cycle were also conducted with five-hour and eight-hour phase advance, which showed a significant effect the first night in improving sleep parameters.

Vanda believes that the timing of the FDA's communication is part of an ongoing violation of the Federal Food Drug, and Cosmetic Act (FDCA). The FDCA requires the FDA to either approve a new drug application or provide an opportunity for a hearing within 180 days after the filing of an application.[1] Because Vanda submitted the sNDA on May 4, 2023, the FDA's deadline under the FDCA was October 31. 2023. The FDA has not complied with the statute and has not timely approved the application or provided an opportunity for a hearing within the statutorily prescribed timeframe. Vanda is also challenging the FDA's approvals of several generic versions of HETLIOZ®, which have been marketed since 2023.

Vanda remains committed to its efforts to hold the FDA accountable to the law, ensuring predictable regulatory conduct.

References

1. 21 U.S.C. § 355(c)(1)

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.

About HETLIOZ®

For full U.S. Prescribing Information for HETLIOZ®, including indication and Important Safety Information, visit www.hetlioz.com.

Corporate Contact:

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com