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): March 13, 2020 (March 12, 2020)

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 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 March 12, 2020, Vanda Pharmaceuticals Inc. (the "Company") received a letter from the U.S. Food and Drug Administration (the "FDA"), in which the FDA notified the Company of its refusal to file the Company's supplemental New Drug Application ("sNDA") for HETLIOZ® for the treatment of Smith-Magenis Syndrome ("SMS"). In the letter, the FDA asserted that the sNDA was not sufficiently complete to permit a substantive review by the FDA. The Company is evaluating next steps and intends to continue to engage with the FDA to determine the regulatory path for HETLIOZ® for the treatment of SMS. The Company believes it has, or can reasonably quickly obtain, the data necessary to complete the resubmission of the sNDA without the need for additional efficacy studies and the letter from the FDA did not request a further efficacy study be performed.

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: March 13, 2020

VANDA PHARMACEUTICALS INC.

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