Vanda Pharmaceuticals Inc.
Form 8-K
April 30, 2019

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): April 30, 2019 (March 14, 2019)

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.

As previously disclosed, in April 2018, Vanda Pharmaceuticals Inc. (the Company) submitted a protocol amendment to the U.S. Food and Drug Administration (the FDA), proposing a 52-week open-label extension (OLE) period for patients who had completed the tradipitant Phase II clinical study (2301) in gastroparesis. In May 2018, based on feedback from the FDA, the Company amended the protocol limiting the duration of treatment in the 2301 study to a total of three months, while continuing to seek further dialogue with the FDA on extending the study duration to 52-weeks. As a part of this negotiation process, in September 2018, the Company submitted a new follow-on 52-week OLE protocol to the FDA (2302) for patients who had completed the 2301 study. While waiting for further feedback, no patients were ever enrolled in any study beyond 12 weeks. On December 19, 2018, the FDA imposed a partial clinical hold (PCH) on the two proposed studies, stating that the Company is required first to conduct additional chronic toxicity studies in canines, monkeys or minipigs before allowing patients access in any clinical protocol beyond 12 weeks. The PCH was not based on any safety or efficacy data related to tradipitant. Rather, the FDA informed the Company that these additional toxicity studies are required by a guidance document.

Also as previously disclosed, on February 5, 2019, the Company filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia (the DC District Court), challenging the FDA s legal authority to issue the PCH, and seeking an order to set it aside. On February 14, 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. On March 14, 2019, the DC District Court granted the FDA s request for voluntary remand and returned the matter to the FDA for further consideration. On April 26, 2019, the FDA provided its remand response, in which it indicated that, after re-evaluation, it believes a partial clinical hold continues to be appropriate. The Company continues to believe that it has provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. On April 29, 2019, the Company and the FDA filed a joint motion for extension of time to propose a scheduling order for this matter, thereby extending the deadline until May 3, 2019 for the FDA and the Company to agree upon and file a proposed scheduling order. The Company intends to continue vigorously pursuing its interests in the matter.

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: April 29, 2019

VANDA PHARMACEUTICALS INC.

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