Vanda Pharmaceuticals Inc. Form 8-K February 06, 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): February 6, 2019 (February 5, 2019)

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-34186 (Commission File No.) 03-0491827 (IRS Employer Identification No.)

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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 7.01. Regulation FD Disclosure.

On February 5, 2019, Vanda Pharmaceuticals Inc. (Vanda) issued a press release announcing the filing of a lawsuit against the U.S. Food and Drug Administration (the FDA). A copy of the press release is filed as Exhibit 99.1 hereto and incorporated by reference herein. On February 5, 2019, Vanda also released an open letter to the FDA. A copy of the open letter is filed as Exhibit 99.2 hereto and incorporated by reference herein.

The information in Item 7.01 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

| No. | Description |
|------|---|
| 99.1 | Press release of Vanda Pharmaceuticals Inc. dated February 5, 2019. |
| 99.2 | Open Letter to the U.S. Food and Drug Administration by Vanda Pharmaceuticals Inc. released February 5, 2019. |

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 6, 2019 VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams Name: Timothy Williams

Senior Vice President, General Counsel and

Title: Secretary