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 23, 2018

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.

On March 23, 2018 (the "Notice Date"), Vanda Pharmaceuticals Inc. ("Vanda") received a Paragraph IV certification notice letter (the "Notice Letter") regarding an Abbreviated New Drug Application ("ANDA") submitted to the U.S. Food and Drug Administration (the "FDA") by Teva Pharmaceuticals USA, Inc. ("Teva") requesting approval to market, sell and use a generic version of the 20mg HETLIOZ® (tasimelton) capsule product for Non-24-Hour Sleep-Wake Disorder.

In its Notice Letter, Teva alleges that U.S. Patent Nos. 9,060,995; 9,539,234; 9,549,913; 9,730,910; 9,855,241 and RE46,604 (collectively, the "Patents"), which cover methods of using HETLIOZ®, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of the product described in its ANDA. The latest of the Patents expires in 2034.

Vanda is currently reviewing the Notice Letter and intends to vigorously enforce its intellectual property rights relating to HETLIOZ®. By statute, Vanda has 45 days from receipt of the Notice Letter to initiate a patent infringement lawsuit against Teva. Such a lawsuit would automatically preclude the FDA from approving Teva's ANDA until the earlier of 30 months from the Notice Date or entry of a district court decision finding the patents invalid, unenforceable or not infringed. The composition and use of HETLIOZ® are currently protected by seven issued patents that are listed in the FDA's Orange Book.

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.

VANDA PHARMACEUTICALS INC.

Dated: March 26, 2018

By: /s/ Richard L. Gulino
Name: Richard L. Gulino
Title: Senior Vice President, General Counsel