

Vanda Pharmaceuticals Inc.
Form 8-K
June 10, 2014

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): June 10, 2014

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))

Item 8.01. Other Events.

On June 10, 2014, Vanda Pharmaceuticals Inc. (Vanda) received a notice of allowance from the United States Patent and Trademark Office (USPTO) for a patent (VAND-0092), application number 13/751,011, covering the method of use of HETLIOZ (tasimelteon) to treat Non-24-Hour Sleep-Wake Disorder (Non-24). The allowed claims relate to the method of treatment as described in the HETLIOZ label that was approved by the U.S. Food and Drug Administration (FDA) and include claims directed to treatment of the totally blind population that has this disorder. Following the expected issuance of the VAND-0092 patent, Vanda intends to submit the patent for listing in the FDA publication *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the Orange Book. The VAND-0092 patent, when issued, would be expected to expire in 2033, thereby potentially extending the exclusivity protection in the U.S. for method of using HETLIOZ in Non-24 beyond the expiration of the U.S. composition of matter patent for HETLIOZ, which is currently expected to expire in 2022.

Various statements in this report are forward-looking statements under the securities laws, including the statements related to the VAND-0092 patent. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Vanda's expectations and projections. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of the action, or inaction, of the USPTO or the FDA, and risks and uncertainties associated with the timing of governmental actions and the protection of Vanda's intellectual property rights and other factors that are described in the Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2013 and quarterly report on Form 10-Q for the quarter ended March 31, 2014, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made in this report after the date thereof, whether as a result of new information, future events or otherwise.

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.

By: /s/ James P. Kelly

Name: James P. Kelly

Title: Senior Vice President, Chief Financial

Officer, Secretary, and Treasurer

Dated: June 10, 2014