# 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): May 24, 2012

# 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.)

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)

ck 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 isions:
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 1.01. Entry into a Material Definitive Agreement.

On May 24, 2012, Vanda Pharmaceuticals Inc. ("Vanda") and Bristol-Myers Squibb ("BMS") entered into an amendment (the "Amendment") to the Amended and Restated License, Development and Commercialization Agreement, dated as of February 25, 2004, as amended, by and between Vanda and BMS relating to certain compounds, including tasimelteon, which Vanda is currently developing for the treatment of circadian rhythm sleep disorders.

Under the Amendment, the parties extended the deadline by which Vanda must enter into a development and commercialization agreement with a third party for tasimelteon until the earliest of: (i) the date mutually agreed upon by both parties following the provision by Vanda to BMS of a full written report of the Phase III clinical studies on which Vanda intends to rely for filing for marketing authorization for tasimelteon in its first major market country (such report, being referred to as the "Phase III report"); (ii) the date of the acceptance by a regulatory authority of the filing by Vanda for marketing authorization for tasimelteon in a major market country following the provision by Vanda to BMS of the Phase III report; or (iii) December 31, 2013.

If Vanda has not entered into such an agreement with respect to certain major market countries by this deadline, then BMS will have the option to develop and commercialize tasimelteon itself in those countries not covered by a development and commercialization agreement on certain pre-determined terms. In addition, the parties extended Vanda's deadline for filing a New Drug Application with the United States Food and Drug Administration for tasimelteon until January 1, 2014.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, a copy of which is filed as Exhibit 10.46 hereto and is hereby incorporated into this report by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

10.46 Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of May 24, 2012.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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: May 30, 2012

### NINTH AMENDMENT TO AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Ninth Amendment to Amended and Restated License, Development and Commercialization Agreement (the "Ninth Amendment") is entered into effective as of May 24, 2012 (the "Effective Date") by and between Vanda Pharmaceuticals Inc., a Delaware corporation ("Vanda") and Bristol-Myers Squibb Company, a Delaware corporation ("BMS").

WHEREAS, Vanda and BMS are parties to that certain Amended and Restated License, Development and Commercialization Agreement effective February 25, 2004, as amended by prior amendments (the "<u>License Agreement</u>") relating to certain compounds including tasimelteon (VEC-162, formerly designated as BMS-214778);

WHEREAS, Vanda and BMS entered into an Amendment to Amended and Restated License, Development and Commercialization Agreement effective as of April 15, 2010 ("Eighth Amendment") that amended and restated certain provisions of the License Agreement;

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, Vanda and BMS agree as follows.

- 1. All capitalized terms used in this Ninth Amendment shall have the meaning ascribed to such terms in the License Agreement, unless otherwise specified herein. Unless otherwise expressly stated, the Sections referred to herein refer to the Sections in the License Agreement.
- 2. Section 3.1.1 of the License Agreement was amended under the Eighth Amendment to extend the period for Vanda to enter into a Development and Commercialization Agreement with a Third Party for a Product containing tasimelteon (VEC-162) under Section 3.1.1 of the License Agreement until May 31, 2013. The parties now desire to further extend this period until the earlier of (a) the commencement of the BMS Option Period as specified in Section 3.2.1 of the License Agreement and (b) December 31, 2013. Accordingly, with respect to a Product containing tasimelteon (VEC-162), Section 3.1.1 is hereby amended such that the amended sentences in Section 3.1.1 shall read as follows (only the amended sentences of Section 3.1.1 are set forth below):
  - If, during the thirty (30) day review period BMS does not formally notify Vanda in writing of its intention to enter into a Development and Commercialization Agreement or informs Vanda that it is not interested in entering into such an agreement or if BMS does notify Vanda of its intention to enter into such an agreement but does not enter into a such an agreement for the Product during such ninety (90) day period of exclusivity, then Vanda shall have until the end of day of the earlier of (a) the day immediately prior to the day that the BMS Option Period commences as specified in Section 3.2.1 and (b) December 31, 2013, to negotiate and enter into a Development and Commercialization Agreement with a Third Party for the Product. If Vanda does not enter into such an agreement with a Third Party prior to the earlier of (i) the commencement of the BMS Option Period as specified in Section 3.2.1 and (ii) January 1, 2014 (the "Option Suspension Date"), then the Vanda Third Party Development Option shall be suspended from the Option Suspension Date until the end of the BMS Option Period for the Product.
- 3. Section 5.2.2 of the License Agreement was amended under the Eighth Amendment to extend the NDA-filing diligence deadline set forth in Section 5.2.2 of the License Agreement until June 1, 2013. In order to allow for the development activity necessary to support an NDA filing, the parties now

desire to further extend this diligence deadline to December 31, 2013. Accordingly, with respect to a Product containing tasimelteon (VEC-162), Section 5.2.2 is hereby amended such that the amended sentence in Section 5.2.2 shall read as follows (only the amended sentence of Section 5.2.2 is set forth below):

In any event, Vanda (a) shall initiate Phase II Clinical Studies for the first Product no later than six (6) months after the Effective Date, (b) shall complete (at least) one Phase II Clinical Study for the first Product no later than twelve (12) months after commencement of the first Phase II Clinical Study (i.e., the date when the first patient in the study is dosed), (c) shall initiate Phase III Clinical Studies for the first Product no later than twenty-four (24) months after completing the first Phase II Clinical Study, and (d) shall file an NDA for the first Product no later than January 1, 2014.

- 4. This Ninth Amendment shall not amend or modify the terms, conditions, rights and obligations of the parties under the License Agreement (as amended), except as specifically set forth herein. The License Agreement (as amended) shall continue in full force and effect in accordance with its terms as amended by this Ninth Amendment.
- 5. This Ninth Amendment may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, BMS and Vanda have caused this Ninth Amendment to be executed by their duly authorized representatives.

#### **BRISTOL-MYERS SQUIBB COMPANY**

By: /s/ Ranya Dajam

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Printed Name: Ranya Dajam
Title: Executive Director, Strategic Transactions
VANDA PHARMACEUTICALS INC.
By: /s/ Mihael H. Polymeropoulos, M.D.
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(Signature of Authorized Representative)
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