# **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 15, 2010

# 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.)

9605 Medical Center Drive Suite 300 Rockville, Maryland 20850

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (240) 599-4500

#### **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))
- o 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 April 15, 2010, 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) May 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 June 1, 2013.

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 10.38 hereto and is hereby incorporated into this report by reference.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
10.38	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 15, 2010.

#### **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/ STEPHANIE R. IRISH

Name: Stephanie R. Irish

Title: Acting Chief Financial Officer, Secretary

and Treasurer

Dated: April 19, 2010

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

This Amendment to Amended and Restated License, Development and Commercialization Agreement (the "<u>Amendment</u>") is entered into effective as of April 15, 2010 (the "<u>Effective Date</u>") by and between Vanda Pharmaceuticals Inc., a Delaware corporation ("<u>Vanda</u>"), and Bristol-Myers Squibb Company, a Delaware corporation ("<u>BMS</u>").

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

WHEREAS, Vanda and BMS desire to amend and restate certain provisions of the License Agreement as set forth herein.

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 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 1.33 of the License Agreement is hereby amended and restated to read in its entirety as follows:
  - "1.33 "*MGH License Agreement*" means the agreement between The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), Vanda and BMS that is currently being negotiated and that will be entered into after the Effective Date, and as it may be modified or supplemented after being entered into, under which Vanda will be obligated to pay MGH certain payments in connection with the development and commercialization of Products."
  - 3. Section 3.1.1 of the License Agreement is hereby amended and restated to read in its entirety as follows:
  - "3.1.1 Vanda Development Option Period. Vanda will have the right, anytime prior to filing an NDA for a Product ("Vanda Third Party Development Option Period"), to negotiate an agreement to sublicense Vanda's rights to Develop and Commercialize a Product (a "Development and Commercialization Agreement") with a Third Party in at least one Major Market Country ("Vanda Third Party Development Option"); provided, however, that with respect to each Product, upon Vanda locking the database for Vanda's first Phase III Clinical Study for the Product, Vanda shall have a limited time in which to exercise the Vanda Third Party Development Option for the Product before the right to exercise such option is suspended. Vanda shall have one hundred twenty (120) days from the date Vanda locks the database for Vanda's first Phase III Clinical Study for the Product to exercise such option. If Vanda exercises such option during such one hundred twenty (120) day period, BMS shall have a right of first negotiation to enter into a Development and Commercialization Agreement for the Product with Vanda. BMS shall have a thirty (30) day review period, from the receipt of Vanda's written notice to seek a Third Party partner, to elect to enter into negotiations with Vanda. During the

thirty (30) day review period, Vanda shall timely provide BMS with copies of any reports, data, results or information, material to the Development of the Product that are or may become available, including but not limited to those relating to the first Phase III Clinical Study for the Product. Thereafter, BMS will have a ninety (90) day period of exclusivity in which to negotiate and execute a Development and Commercialization Agreement, and Vanda shall negotiate in good faith during such ninety (90) day period. During such thirty (30) day review period and such ninety (90) day period of exclusivity, Vanda shall not approach any Third Party concerning a Development and Commercialization Agreement or disclose any of the Phase III Clinical Study data. results or conclusions to any Third Party that may potentially enter into a Development and Commercialization Agreement for the Product. 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) May 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) June 1, 2013 (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. The Vanda Third Party Development Option is exercisable by written notice from Vanda to BMS of Vanda's intention to seek a Third Party partner. Such option shall be exercisable on a Product-by-Product and on a Major Market Country-by-Major Market Country basis. For the avoidance of doubt, rights to Develop and Commercialize a Product in non-Major Market Countries may be included in the Development and Commercialization Agreement for a Major Market Country. With respect to a Product, the Major Market Countries together with all other countries that are not included in a Development and Commercialization Agreement for the Product shall be referred to as the "Remaining Countries."

#### 4. Section 3.2.1 of the License Agreement is hereby amended and restated to read in its entirety as follows:

"3.2.1 BMS Option Period. The BMS Option Period for a Product will commence for the Remaining Countries (providing Vanda has not entered into one or more Development and Commercialization Agreements for the Product which when taken together include all of the Major Market Countries prior to the Option Suspension Date for the Product) on the date that (1) Vanda provides BMS with a full written report of the Phase III Clinical Studies, including the results and conclusions thereof, on which Vanda intends to rely for filing for Marketing Authorization for the Product in the first Major Market Country and (2) either (i) both Parties agree in writing is the commencement date for the BMS Option Period or (ii) there is acceptance by the applicable Regulatory Authority of the filing of a Marketing Authorization for the Product in a Major Market Country. The BMS Option Period shall terminate ninety (90) days later ("BMS Option Period"). At any time during the BMS Option Period, BMS may provide Vanda with written notice that either: (a) it does not wish to Develop or Commercialize the Product in the Remaining Countries; or (b) it wishes to reacquire all rights to the Product in the Remaining Countries ((b) shall be referred to as the "BMS Option"). Such option shall be exercisable on a Product-by-Product basis. For the avoidance of doubt, if BMS does not exercise the BMS Option for the Remaining Countries within the BMS Option Period, then upon completion of the BMS Option Period, the Vanda Third Party Development Option Period."

- 5. Section 5.2.2 of the License Agreement is hereby amended and restated to read in its entirety as follows::
- "5.2.2 As soon as reasonably practicable after the Effective Date, Vanda shall commence Phase II Clinical Studies of the Product in accordance with the Development Plan set forth in Schedule 1.19 and this Agreement. 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 June 1, 2013. In the event that any of such milestones are missed, it shall be deemed a material breach of this Agreement for the purposes of Article 13. BMS' ability to terminate this Agreement pursuant to Section 13.2 shall apply without regard to whether any circumstances falling within Section 14.4 might otherwise excuse (in whole or in part) any inability or failure to meet any such milestones. If Vanda misses any of the above milestone dates, Vanda may request that BMS grant a reasonable extension to allow it to meet such milestone, and BMS agrees that it will not unreasonably withhold its assent to any such reasonable revision where supported by clear evidence that Vanda has been making good faith and diligent efforts to achieve the milestones but has failed as a result of technical difficulties or delays that the parties could not have reasonably avoided in the achievement of such milestones; and provided, that BMS may also need to seek approval of MGH in such event, and any approval by BMS shall further be conditioned on receipt of approval of MGH."
- 6. This 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 Amendment.
- 7. This 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 Amendment to be executed by their duly authorized representatives.

# **BRISTOL-MYERS SQUIBB COMPANY**

By: /s/ Graham R. Brazier

(Signature of Authorized Representative)

Printed Name: Graham R. Brazier

Title: Vice President Strategic Transactions Group

#### VANDA PHARMACEUTICALS INC.

By: /s/ Gunther Birznieks

(Signature of Authorized Representative)

Printed Name: Gunther Birznieks

Title: Vice President, Business Development