

---

---

**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 2, 2016

---

**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)

---

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 1.01. Entry into a Material Definitive Agreement.**

On February 2, 2016, Vanda Pharmaceuticals Inc. (“Vanda”) entered into an agreement (“Agreement”) with Aventisub LLC, a subsidiary of Sanofi-Aventis (“Sanofi”), and Titan Pharmaceuticals, Inc. (“Titan”) relating to Fanapt®. Vanda is the exclusive sublicensee of certain patents and know-how from Titan pursuant to that certain Sublicense Agreement, dated as of November 20, 1997, which was previously assigned from Novartis Pharma A.G. to Vanda in 2014 (the “Sublicense Agreement”); Sanofi is the ultimate licensor of certain patents and know-how to Titan pursuant to that certain Worldwide License Agreement between Sanofi and Titan, dated as of December 31, 1996 (“License Agreement”).

The Agreement amends the License Agreement and Sublicense Agreement to, among other things, remove Titan as the entity through which royalty payments from Vanda are directed to Sanofi following the expiration of the new chemical entity (NCE) patent for Fanapt® in the US on November 15, 2016. Under the Agreement, Vanda would pay directly to Sanofi a fixed royalty of 3% of net sales from November 16, 2016 through December 31, 2019 relating to manufacturing know-how. Vanda will make a non-refundable pre-payment of \$2,000,000 applied to this 3% manufacturing know-how royalty and will make additional royalty payments only to the extent that Vanda’s cumulative royalty obligations during this period exceed the amount of the pre-payment. No further royalties on manufacturing know-how are payable by Vanda after December 31, 2019. The Agreement does not alter Titan’s obligation under the License Agreement to make royalty payments to Sanofi prior to November 16, 2016 or Vanda’s obligation under the Sublicense Agreement to pay to Sanofi a fixed royalty on Fanapt® net sales equal to 6% on Sanofi know-how not related to manufacturing under certain conditions.

The foregoing is only a brief description of the material terms of the Agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Agreement that is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
10.1	Agreement, dated February 2, 2016 by and among Titan Pharmaceuticals, Inc., Aventisub LLC and Vanda Pharmaceuticals Inc.

**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 and  
Treasurer

Dated: February 4, 2016

**AGREEMENT**

THIS AGREEMENT (the "Agreement") is made as of February 2, 2016 (the "Effective Date") by and among, Titan Pharmaceuticals, Inc., a Delaware corporation ("Titan"), Aventisub LLC, a Delaware limited liability company, the successor-in-interest to Aventisub II Inc. ("Sanofi-Aventis") and Vanda Pharmaceuticals Inc., a Delaware corporation ("Vanda") All entities identified above shall be collectively referred to as the "Parties" and individually as a "Party".

**WITNESSETH:**

**WHEREAS**, Sanofi-Aventis, as successor to Hoechst Marion Roussel, Inc. ("HMRI"), and Titan are parties to a Worldwide License Agreement, effective as of December 31, 1996 (the "HMRI License Agreement"), as amended (the "License Agreement");

**WHEREAS**, pursuant to the License Agreement, Titan and Vanda, as assignee from Novartis Pharma AG, are parties to that certain Iloperidone Sublicense Agreement, effective as of November 20, 1997, as amended (the "Sublicense Agreement");

**WHEREAS**, the Parties wish to address the payment of the three percent (3%) royalty for KNOW-HOW to manufacture COMPOUND and PRODUCT that is payable by Titan to Sanofi-Aventis pursuant to Section 3.4 of the License Agreement in certain circumstances; and

**WHEREAS**, the Parties also wish to confirm that Vanda shall be solely responsible to pay the amounts payable to Sanofi-Aventis as set forth in this Agreement.

**NOW THEREFORE**, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration the receipt of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Definitions.** Capitalized terms used but not otherwise defined herein shall have the meanings given them in the License Agreement. For purposes of clarification, references to "HMRI" in the License Agreement refer to Aventisub LLC, as the successor-in-interest to HMRI.

2. **Payments.** Notwithstanding anything in the License Agreement to the contrary, the Parties agree as follows:

(a) In lieu of payment of a three percent (3%) royalty by Titan to Sanofi-Aventis for KNOW-HOW to manufacture the COMPOUND and PRODUCT as described in Section 3.4(ii) of the License Agreement, (i) Titan shall pay to Sanofi-Aventis an amount equal to three percent (3%) of NET SALES of the PRODUCT (the "Payment") from the Effective Date up to November 15, 2016, in each case on TITAN's, its AFFILIATES' and SUBLICENSEES' annual NET SALES in the U.S. and (ii) Vanda shall directly pay to Sanofi-Aventis the Payment from and including November 16, 2016 until and including December 31, 2019 on VANDA's, its AFFILIATES' and SUBLICENSEES' annual NET SALES in the TERRITORY.

Notwithstanding the foregoing, within ten (10) days following full execution of this Agreement, Vanda shall pre-pay to Sanofi-Aventis two million U.S. dollars (US\$2,000,000) against Payments that will be due and owing pursuant to Section 2(a)(ii) (the "Pre-Payment"). Any Payments that become due from Vanda pursuant to Section 2(a)(ii) shall be credited against the Pre-Payment until the full amount of the Pre-Payment has been offset by Payments due and owing by Vanda hereunder. To the extent the Payments due and owing by Vanda pursuant to Section 2(a)(ii) from and including November 16, 2016 until and including December 31, 2019, exceed two million U.S. dollars (US\$2,000,000) prior to December 31, 2019, Vanda shall pay to Sanofi-Aventis the Payment as set forth herein for the amounts due and owing in excess of two million U.S. dollars (US\$2,000,000). If the actual Payments owing by Vanda to Sanofi-Aventis pursuant to Section 2(a)(ii) do not exceed the Pre-Payment, Sanofi-Aventis shall be entitled to retain any amounts remaining of the Pre-Payment.

(b) In addition to the foregoing, within ten (10) days following full execution of this Agreement, Vanda will pay to Sanofi-Aventis an initial payment equal to three percent (3%) of NET SALES for PRODUCT sold in Mexico and Israel from the date that patent protection for the PATENTS claiming a priority date of May 19, 1989 and December 29, 1989 in each such country expired through the Effective Date of this Agreement. Thereafter, Vanda shall pay to Sanofi-Aventis the Payment from the date that patent protection for the PATENTS claiming a priority date of May 19, 1989 and December 29, 1989 in a country in the TERRITORY expired through December 31, 2019, except to the extent that the Payment is otherwise made in accordance with Section 2(a) above.

(c) For clarity, the amounts payable/creditable pursuant to Sections 2(a) and (b) of this Agreement are payable/creditable on the dates and manner described in the License Agreement. Such payments are in lieu of any royalties for KNOW-HOW to manufacture COMPOUND and PRODUCT set forth in the License Agreement, which is deemed to be amended by this Agreement. Such amounts are payable regardless of whether Titan or Vanda, as applicable, utilize, rely upon, or otherwise require the KNOW-HOW to manufacture COMPOUND and PRODUCT. Vanda shall indemnify Titan for payments that Vanda is obligated to make directly to Sanofi under Section 2(a)(ii) or 2(b) hereof.

(d) Following receipt of the amounts contemplated under this Agreement, the license for use of KNOW-HOW to manufacture COMPOUND and PRODUCT will be on a world-wide, fully-paid, royalty-free, irrevocable basis, and no further royalties or other amounts on KNOW-HOW to manufacture COMPOUND and PRODUCT would be due worldwide.

(e) For purposes of clarity, nothing in this Agreement alters (i) Vanda's obligation to pay directly to Sanofi royalties for Know-How not related to Manufacturing in any country of the TERRITORY pursuant to the terms of the Sublicense Agreement or (ii) Titan's obligations under Section 3.4(i), 3.5 and 3.6 of the License Agreement.

(f) By way of illustration, in the United States, PATENTS claiming a priority date of May 19, 1989 and December 29, 1989 will expire on November 15, 2016, accordingly, the royalties payable to Sanofi-Aventis under the License Agreement, as amended by this Agreement, for sales of PRODUCT in the TERRITORY would be as follows:

(i) From the Effective Date through November 15, 2016, Titan would pay to Sanofi-Aventis an amount equal to fifteen percent (15%) on NET SALES in the United States equal (i.e., both the royalty payable in respect of the PATENTS and KNOW-HOW and the Payment).

(ii) From November 16, 2016 through December 31, 2019, Vanda would pay directly to Sanofi-Aventis an amount equal to nine percent (9%) on NET SALES in the United States (i.e., the Payment and the royalty on KNOW-HOW not relating to manufacturing, pursuant to Section 3.5 of the License Agreement), provided that the Payments (i.e. three percent (3%) of NET SALES) would be credited against the Pre-Payment, and to the extent Payments exceed the Pre-Payment, Vanda would pay such Payments directly to Sanofi-Aventis for amounts due and owing in excess of two million U.S. dollars (US\$2,000,000).

(iii) From January 1, 2020 through November 15, 2026, Vanda would pay directly to Sanofi-Aventis an amount equal to six percent (6%) on NET SALES in the United States (i.e., only the royalty on KNOW-HOW not relating to manufacturing pursuant to Section 3.5 of the License Agreement).

(g) For purposes of clarification, each payment made by Vanda hereunder will be governed by terms and conditions set forth Article 9 of the License Agreement. In the event of any dispute or disagreement with respect to this Agreement, the applicable Parties agree to discuss the issue in good faith prior to instituting any action for breach hereunder. Titan, Sanofi-Aventis and Vanda agree that Section 14 of the License Agreement shall apply to any disputes between or among the Parties to this Agreement.

### 3. Miscellaneous.

(a) Amendments. All references to the License Agreement shall be deemed to refer to the License Agreement as amended hereby, and the terms of this Agreement are hereby incorporated into the License Agreement. Except as amended hereby, the License Agreement shall remain in full force and effect. Vanda shall be deemed to be a party to the License Agreement solely to the extent specified in this Agreement.

(b) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of Titan, Sanofi-Aventis, Vanda and each of their respective successors and assigns.

(c) Governing Law. Section 14 of the License Agreement sets forth the governing law and jurisdiction sections applicable to this Agreement.

*[remainder of the page intentionally blank]*

IN WITNESS WHEREOF, the Parties hereby have executed this Agreement by proper persons thereunto duly authorized as of the Agreement Effective Date.

**AVENTISUB LLC**

By: /s/ Joseph M. Palladino  
Name: Joseph M. Palladino  
Title: President

**TITAN PHARMACEUTICALS, INC.**

By: /s/ Sunil Bhonsle  
Name: Sunil Bhonsle  
Title: President & CEO

**VANDA PHARMACEUTICALS INC.**

By: /s/ Mihael Polymeropoulos  
Name: Mihael Polymeropoulos  
Title: CEO