

Vanda Pharmaceuticals Inc.
Form 8-K
October 14, 2009

**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): October 12, 2009

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-51863

(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))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01. Entry into a Material Definitive Agreement.

On October 12, 2009, Vanda Pharmaceuticals Inc. (Vanda) announced that it had entered into an Amended and Restated Sublicense Agreement (the Agreement) with Novartis Pharma AG (Novartis). The parties had originally entered into a sublicense agreement on June 4, 2004 (as amended, the Original Agreement) pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to a compound known as iloperidone. On May 6, 2009, the U.S. Food and Drug Administration (FDA) granted marketing approval of the oral formulation of iloperidone for the acute treatment of adult patients with schizophrenia pursuant to Vanda s New Drug Application (the NDA).

Pursuant to the Agreement, Novartis will have exclusive commercialization rights to all formulations of iloperidone (Fanapt) in the United States and Canada (the Territory). Except for two post-approval studies started by Vanda prior to the execution date of the Agreement, which Vanda is obligated to complete, Novartis will be responsible for the further clinical development activities in the Territory, including the development and commercialization of a long acting injectable (or depot) formulation of Fanapt . In connection with such rights, Vanda granted Novartis an exclusive license to all know-how owned or licensed by Vanda that may be necessary or useful in the development or commercialization of Fanapt for the Territory, as well as an exclusive license to the trademark Fanapt for use in the Territory. In addition, Vanda assigned the NDA to Novartis and agreed that all future regulatory interactions with the FDA would be the exclusive responsibility of Novartis.

Pursuant to the terms of the Agreement, Vanda will be entitled to an upfront payment of \$200 million and will be eligible for additional payments totaling up to \$265 million upon the achievement of certain commercial and development milestones for Fanapt in the Territory. Vanda will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt in the Territory. In addition, Vanda will no longer be required to make the future milestone and royalty payments that were contemplated in the Original Agreement with respect to sales of Fanapt in the Territory.

Vanda retains exclusive rights to Fanapt outside the Territory and Vanda will have exclusive rights to use any of Novartis data for Fanapt for developing and commercializing Fanapt outside the Territory. At Novartis option, the parties will enter into good faith discussions relating to the co-commercialization of Fanapt outside of the Territory or, alternatively, Novartis will receive a royalty on net sales of Fanapt outside of the Territory.

The Agreement is subject to customary regulatory approvals.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 12, 2009.

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.

Date: October 14, 2009

VANDA PHARMACEUTICALS INC.

By: /s/ Stephanie R. Irish

Name: Stephanie R. Irish

Title: Acting Chief Financial Officer and
Treasurer