**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** | **03-0491827** |
|---|---|
| (Commission File No.) | (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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o 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 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 injectible (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

**Exhibit 99.1**

**Vanda Pharmaceuticals Enters into an Exclusive License Agreement for the Commercialization and Development of Fanapt™ in the U.S. and Canada for the Treatment of Schizophrenia**

ROCKVILLE, MD October 12, 2009— Vanda Pharmaceuticals Inc. (NASDAQ: VNDA) announced today that it has entered into an agreement with Novartis Pharma AG to commercialize and develop Fanapt™ (iloperidone), Vanda's anti-psychotic, in the U.S. and Canada. Fanapt™ was approved by the U.S. Food and Drug Administration on May 6, 2009 for the acute treatment of schizophrenia in adults. Fanapt™ is a mixed dopamine D2 / serotonin 5HT2A receptor antagonist. The U.S. anti-psychotic market is approximately $14 billion.

Under the terms of the agreement, which amended and restated a prior agreement among the parties, Novartis will have exclusive commercialization rights to Fanapt™ for the U.S. and Canada. Novartis will be responsible for the further clinical development activities in these territories, including the development and commercialization of a long-acting injectable (or depot) formulation of Fanapt™. Vanda will retain rights to commercialize Fanapt™ oral and depot formulations outside the U.S. and Canada. At Novartis' option, the parties will enter into good faith discussions relating to an agreement for the co-commercialization of Fanapt™ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales.

Under the agreement, Vanda will receive an upfront payment of $200 million and will be eligible for additional payments totaling up to $265 million upon the achievement of certain development and commercial milestones for Fanapt™ in the U.S. and Canada. Vanda will also receive royalties on the U.S. and Canadian net sales of Fanapt™. The consummation of the transaction is subject to the receipt of customary regulatory approvals, which are expected by the end of 2009.

"I am very excited about our agreement with Novartis, as we now have one of the premier pharmaceutical companies in the world to commercialize the oral formulation and further develop and commercialize the depot formulation of Fanapt™ in the U.S. and Canada" said Mihael H. Polymeropoulos, M.D., Vanda's Chief Executive Officer. "This agreement allows Vanda to utilize current and future data generated by Novartis on the oral and depot formulations to pursue regulatory approvals outside the U.S and Canada."

Cowen and Company, LLC acted as financial advisor to Vanda.

**About Schizophrenia**

Schizophrenia is a chronic debilitating disorder which affects more than two million Americans, and millions more worldwide. While significant progress has been made in understanding the disease and developing treatments, there remains a significant unmet medical need.

**About Fanapt™**

**Important Safety Information**

Fanapt™ is indicated for the acute treatment of schizophrenia in adults.

**Increased Mortality: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death compared to placebo. Fanapt™ is not approved for the treatment of patients with dementia-related psychosis.**

QT Prolongation: In an open-label QTc study in patients with schizophrenia or schizoaffective disorder (N=160), Fanapt™ was associated with QTc prolongation of 9 msec at an iloperidone dose of 12 mg twice daily. This affect was augmented by the presence of CYP450, 2D6 or 3A4 metabolic inhibition. The use of Fanapt™ should be avoided in combination with other drugs that are known to prolong QTc. Caution is warranted when prescribing Fanapt™ with drugs that inhibit Fanapt™ metabolism.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex, has been reported in association with administration of antipsychotic drugs. Clinical manifestations include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure.

Tardive Dyskinesia (TD): The risk of developing TD and the likelihood for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose increases. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Given these considerations Fanapt™ should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia.

Hyperglycemia and Diabetes Mellitus: Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Fanapt™. Patients with risk factors for diabetes mellitus who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of and during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Weight Gain: Based on the pooled data from the four placebo-controlled, 4- or 6-week, fixed- or flexible-dose studies, the proportions of patients having a weight gain of ³ 7% body weight was 12% for Fanapt™ 10-16 mg/day, 18% for Fanapt™ 20-24 mg/day, and

13% for Fanapt™ (combined doses) versus 4% for placebo.

Seizures: In short-term placebo-controlled trials (4- to 6-weeks), seizures occurred in 0.1% (1/1344) of patients treated with Fanapt™ compared to 0.3% (2/587) on placebo. As with other antipsychotics, Fanapt™ should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold.

Orthostatic Hypotension and Syncope: Fanapt™ can induce orthostatic hypotension and syncope. Fanapt™ should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that predispose the patient to hypotension.

Leukopenia, Neutropenia, and Agranulocytosis: In clinical trial and postmarketing experience, events of leukopenia/neutropenia have been reported temporally related to antipsychotic agents. Agranulocytosis (including fatal cases) have been reported. Patients with a pre-existing low white blood cell count (WBC) or a history of leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue Fanapt™ at the first sign of a decline in WBC in the absence of other causative factors.

Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, Fanapt™ elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients receiving prolactin-elevating compounds.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing Fanapt™ for patients who will be experiencing conditions which may contribute to an elevation in core body temperature.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia.

Suicide: The possibility of suicide attempt is inherent in psychotic illnesses, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for Fanapt™ should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

Priapism: Three cases of priapism were reported in the pre-marketing Fanapt™ program. Severe priapism may require surgical intervention

Potential for Cognitive and Motor Impairment: Fanapt™, like other antipsychotics, has the potential to impair judgement, thinking, or motor skills. Patients should be cautioned about performing activities requiring mental alertness, such as operating hazardous machinery or operating a motor vehicle, until they are reasonably certain that Fanapt™ therapy does not affect them adversely.

Common adverse reactions include dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia and weight increased.

For additional warnings, precautions and complete prescribing information, go to Vanda's web site: www.fanapt.com.

**About Vanda**

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of clinical-stage products for central nervous system disorders. For more on Vanda, please visit http://www.vandapharma.com.

**CONFERENCE CALL**

The company has scheduled a conference call for tomorrow, Tuesday, October 13, 2009, at 8:30 AM ET. During the call, Mihael H. Polymeropoulos, M.D., President and CEO and Stephanie R. Irish, Acting Chief Financial Officer, will discuss the Agreement with Novartis on Fanapt™. Investors can call 1-866-730-5767 (domestic) and 1-857-350-1591 (international) prior to the 8:30 AM ET start time and ask for the Vanda Pharmaceuticals conference call (Participant Passcode 96412945) hosted by Dr. Polymeropoulos.

A replay of the call will be available Tuesday, October 13, 2009, at 11:30 AM ET and will be accessible until Tuesday, October 20, 2009. The replay call-in number is 1-888-286-8010 for domestic callers and 1-617-801-6888 for international callers. The access number is 76078163.

The conference call will be broadcast simultaneously on Vanda's Web site, http://www.vandapharma.com. Investors should click on the Investor Relations tab and are advised to go to the Web site at least 15 minutes early to register, download, and install any necessary software. The call will also be archived on the Vanda Web site for a period of 30 days, through Thursday, November 12, 2009.

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Various statements in this release are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vanda Pharmaceuticals Inc. is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in the company's forward-looking statements include, among others: the extent and effectiveness of the development, sales and marketing and distribution support Fanapt™ receives; Vanda's ability to successfully commercialize Fanapt™ outside of the U.S. and Canada; delays in the completion of Vanda's clinical trials; a failure of Vanda's products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements for its products; a lack of acceptance of

Vanda's products in the marketplace, or a failure to become or remain profitable; Vanda's expectations regarding trends with respect to its costs and expenses; Vanda's inability to obtain the capital necessary to fund its commercial and research and development activities; Vanda's failure to identify or obtain rights to new products; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; a loss of any of Vanda's key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda's products under its license and sublicense agreements and other factors that are described in the "Risk Factors" section (Part II, Item 1A) of Vanda's quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2009 (File No. 001-34186). In addition to the risks described above and in Part II, Item 1A of Vanda's quarterly report on Form 10-Q, 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.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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