

---

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): November 2, 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))
- 
-

**Item 2.02. Results of Operations and Financial Condition.**

On November 2, 2009, Vanda Pharmaceuticals Inc. issued a press release relating to its results of operations and financial condition for the third quarter ended September 30, 2009. The full text of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated November 2, 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.

VANDA PHARMACEUTICALS INC.

By: /s/ STEPHANIE R. IRISH

Name: Stephanie R. Irish

Title: Acting Chief Financial Officer and Treasurer

Dated: November 2, 2009

**Not For Immediate Release****Company Contact:**

Stephanie R. Irish  
Acting Chief Financial Officer  
Vanda Pharmaceuticals Inc.  
(240) 599-4500  
stephanie.irish@vandapharma.com

**Vanda Pharmaceuticals Reports Third Quarter 2009 Results**

**ROCKVILLE, MD.** — November 2, 2009 — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of clinical-stage products for central nervous system disorders, today announced financial and operational results for the third quarter ended September 30, 2009.

Vanda reported a net loss of \$7.7 million for the third quarter of 2009, compared to \$12.4 million for the second quarter of 2009 and \$10.9 million for the third quarter of 2008. Total expenses for the third quarter of 2009 were \$7.7 million, compared to \$12.4 million for the second quarter of 2009 and \$11.2 million for the third quarter of 2008. Research and development (R&D) expenses for the third quarter of 2009 were \$2.1 million, compared to \$7.2 million for the second quarter of 2009 and \$3.8 million for the third quarter of 2008. The decrease in R&D expenses in the third quarter of 2009 relative to the second quarter of 2009 is primarily due to the regulatory consulting fees accrued in the second quarter as a result of the approval of Fanapt™ (iloperidone) by the U.S. Food and Drug Administration (FDA). The decrease in R&D expenses in the third quarter of 2009 relative to the third quarter of 2008 is primarily due to the completion of the Phase III clinical trial of tasimelteon in chronic primary insomnia in 2008.

As of September 30, 2009, Vanda's cash, cash equivalents, and marketable securities totaled approximately \$20.7 million. As of September 30, 2009, a total of approximately 27.2 million shares of Vanda common stock were outstanding. Net loss per common share for the third quarter of 2009 was \$0.28, compared to \$0.46 for the second quarter of 2009 and \$0.41 for the third quarter of 2008.

**OPERATIONAL HIGHLIGHTS**

On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis Pharma AG (Novartis). The parties had originally entered into a sublicense agreement on June 4, 2004 pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to Fanapt™. The agreement is subject to, and will become effective upon, clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act), which is expected by the end of 2009.

Pursuant to the agreement, Novartis will have exclusive commercialization rights to all formulations of Fanapt™ in the U.S. and Canada. 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 U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanapt™.

Pursuant to the terms of the agreement, Vanda will be entitled to an upfront payment of \$200 million, which it expects to receive within 30 days after the effective date of the agreement. Vanda will be eligible for additional payments totaling up to \$265 million upon the achievement of certain commercial and development milestones for Fanapt™ in the U.S. and Canada. 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 U.S. and Canada. In addition, Vanda will no longer be required to make any future milestone payments with respect to sales of Fanapt™ or any future royalty payments with respect to sales of Fanapt™ in the U.S. and Canada.

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

Vanda continued the clinical, regulatory and commercial evaluation for tasimelteon, a MT1/MT2 melatonin agonist, currently in Phase III stage of development.

#### **FINANCIAL DETAILS**

- Operating Expenses. Third quarter 2009 R&D expenses of \$2.1 million consisted primarily of \$0.5 million of salaries and benefits, \$0.7 million of non-cash stock based compensation costs for R&D personnel, \$0.2 million for the carcinogenicity study and \$0.2 million in consulting fees. This compares to \$7.2 million for the second quarter of 2009 and \$3.8 million for the third quarter of 2008. The decrease in R&D expenses in the third quarter of 2009 relative to the second quarter of 2009 is primarily due to the regulatory consulting fees accrued in the second quarter as a result of the approval of Fanapt™ by the FDA. The decrease in R&D expenses in the third quarter of 2009 relative to the third quarter of 2008 is primarily due to the completion of the Phase III clinical trial of tasimelteon in chronic primary insomnia in 2008.
- General and administrative (G&A) expenses of \$5.3 million for the third quarter of 2009 consisted primarily of \$0.4 million of salaries and benefits and \$2.6 million of non-cash stock based compensation costs for G&A personnel, as well as \$0.5 million of legal fees, \$0.7 million of commercial costs and \$0.2 million of insurance costs. This compares to \$5.0 million for the second quarter of 2009 and \$7.4 million for the third quarter of 2008. The decrease in G&A expenses in the third quarter of 2009 relative to the third quarter of 2008 is primarily due to lower stock-based compensation and commercial expenses.
- Employee stock-based compensation expense recorded in the third quarter of 2009 totaled \$3.3 million. Of these non-cash charges, \$0.7 million was recorded as R&D expense and \$2.6 million was recorded as G&A expense. For the second quarter of 2009 and the third quarter of 2008, total stock-based compensation expense was \$2.8 million and \$3.6 million, respectively. The increase in stock-based compensation expense in the third quarter of 2009 relative to the second quarter of 2009 is the result of the issuance of additional non-

qualified stock options in 2009. The decrease in stock-based compensation expense in the third quarter of 2009 relative to the third quarter of 2008 is primarily due to a lower stock-based compensation expense resulting from the workforce reduction in the fourth quarter of 2008.

- Cash and marketable securities decreased by \$8.3 million during the third quarter of 2009. Changes included \$7.7 million of net losses, increases of \$0.5 million in inventory, decreases in accrued expenses and accounts payable of \$2.9 million, increases in prepaid expenses of \$1.5 million, offset by \$3.9 million in non-cash depreciation, amortization, and stock-based compensation expense and \$0.4 million in proceeds from the exercise of stock options.
- Vanda's cash, cash equivalents and marketable securities as of September 30, 2009 totaled approximately \$20.7 million, compared to approximately \$46.5 million as of December 31, 2008.
- Net loss for the third quarter of 2009 was \$7.7 million, compared to a net loss of \$12.4 million for the second quarter of 2009 and a net loss of \$10.9 million for the third quarter of 2008.
- Net loss per common share for the third quarter of 2009 was \$0.28, compared to \$0.46 for the second quarter of 2009 and \$0.41 for the third quarter of 2008.

#### **FINANCIAL GUIDANCE**

Vanda is currently concentrating its efforts on the transition of the commercialization and development rights to Fanapt™ in the U.S. and Canada to Novartis and expects to work closely on the joint steering committee to assist in the anticipated commercial launch of Fanapt™ in the first quarter of 2010. The transition includes all regulatory, manufacturing and post-marketing commitments requested by the FDA. Under the terms of the agreement with Novartis, except for two small 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 U.S. and Canada, including the development and commercialization of a depot formulation of Fanapt™. In addition, the Company will also evaluate the regulatory path and commercial opportunity for Fanapt™ outside the U.S. and Canada. Vanda will also continue the clinical, regulatory and commercial evaluation for tasimelteon. The Company intends to operate on a reduced spending plan with its fixed overhead costs expected to be approximately \$2.5 million to \$3 million per quarter.

#### **CONFERENCE CALL**

Vanda has scheduled a conference call for today, Monday, November 2, 2009, at 10:00 AM ET. During the call, Mihael H. Polymeropoulos, M.D., President and CEO, and Stephanie Irish, Acting CFO, will discuss quarterly results and other corporate activities. Investors can call 1-800-901-5247 (domestic) and 1-617-786-4501 (international) prior to the 10:00 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos (participant passcode 46702701). A replay of the call will be available Monday, November 2, 2009, at 1:00 PM ET and will be accessible until Monday, November 9, 2009, at 5:00 PM ET. 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 87052099.

The conference call will be broadcast simultaneously on the company'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 December 2, 2009.

**ABOUT VANDA PHARMACEUTICALS INC.:**

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 Pharmaceuticals Inc., please visit <http://www.vandapharma.com>.

**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.

#####

**VANDA PHARMACEUTICALS INC.**  
**(A Development Stage Enterprise)**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Cost of sales	376,792	—	606,143	—
Research and development	2,091,984	3,792,424	11,620,918	20,375,998
General and administrative	5,266,434	7,400,263	14,478,786	24,814,462
Total operating expenses	<u>7,735,210</u>	<u>11,192,687</u>	<u>26,705,847</u>	<u>45,190,460</u>
Loss from operations	(7,735,210)	(11,192,687)	(26,705,847)	(45,190,460)
Interest income	9,842	323,476	84,391	1,630,238
Net loss	<u>\$ (7,725,368)</u>	<u>\$ (10,869,211)</u>	<u>\$ (26,621,456)</u>	<u>\$ (43,560,222)</u>
Basic and diluted net loss per share attributable to common stockholders	<u>\$ (0.28)</u>	<u>\$ (0.41)</u>	<u>\$ (0.99)</u>	<u>\$ (1.63)</u>
Shares used in calculation of basic and diluted net loss per share attributable to common stockholders	<u>27,196,694</u>	<u>26,650,534</u>	<u>26,920,742</u>	<u>26,649,439</u>



**VANDA PHARMACEUTICALS INC.**  
**(A Development Stage Enterprise)**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

	<u>September 30, 2009</u>	<u>December 31, 2008</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,417,647	\$ 39,079,304
Marketable securities	3,265,175	7,378,798
Prepaid expenses, deposits and other current assets	2,632,783	1,287,400
Inventory	1,758,427	—
Total current assets	25,074,032	47,745,502
Property and equipment, net	1,411,326	1,758,111
Restricted cash	430,230	430,230
Intangible asset, net	11,393,857	—
Total assets	\$ 38,309,445	\$ 49,933,843
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,346,236	\$ 512,382
Accrued expenses	2,046,028	2,898,417
Total current liabilities	8,392,264	3,410,799
Long-term liabilities:		
Deferred rent	505,831	502,770
Total liabilities	8,898,095	3,913,569
Stockholders' equity:		
Common stock	27,202	26,653
Additional paid-in capital	280,980,068	270,988,157
Accumulated other comprehensive income (loss)	43	(20,029)
Deficit accumulated during the development stage	(251,595,963)	(224,974,507)
Total stockholders' equity	29,411,350	46,020,274
Total liabilities and stockholders' equity	\$ 38,309,445	\$ 49,933,843

**VANDA PHARMACEUTICALS INC.**  
**(A Development Stage Enterprise)**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

	Nine Months Ended	
	September 30, 2009	September 30, 2008
<b>Cash flows from operating activities:</b>		
Net loss	\$(26,621,456)	\$(43,560,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	346,785	403,141
Employee and non-employee stock-based compensation	8,708,726	12,679,311
Loss on disposal of assets	—	(173)
Amortization of net discounts on short-term investments	122,963	(212,664)
Amortization of intangible assets	606,143	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(1,345,383)	(1,160,103)
Inventory	(1,758,427)	—
Accounts payable	833,854	(2,089,044)
Accrued expenses	(852,389)	(6,708,552)
Other liabilities	3,061	142,732
Net cash used in operating activities	<u>(19,956,123)</u>	<u>(40,505,574)</u>
<b>Cash flows from investing activities:</b>		
Acquisition of intangible asset	(7,000,000)	—
Purchases of property and equipment	—	(943,659)
Purchases of marketable securities	(11,365,815)	(11,491,577)
Proceeds from sales of marketable securities	126,547	10,373,251
Maturities of marketable securities	15,250,000	42,060,000
Net cash provided by (used in) investing activities	<u>(2,989,268)</u>	<u>39,998,015</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options, warrants and restricted stock units	1,283,734	—
Net cash provided by financing activities	<u>1,283,734</u>	<u>—</u>
Effect of foreign currency translation	—	16,745
Net change in cash and cash equivalents	(21,661,657)	(490,814)
Cash and cash equivalents, beginning of period	39,079,304	41,929,533
Cash and cash equivalents, end of period	<u>\$ 17,417,647</u>	<u>\$ 41,438,719</u>
<b>Supplemental disclosure of non-cash investing activities</b>		
Intangible asset acquisition included in accounts payable	\$ 5,000,000	—

SOURCE Vanda Pharmaceuticals Inc.

**11/2/2009**

CONTACT: Stephanie R. Irish, Acting Chief Financial Officer of Vanda Pharmaceuticals Inc.,  
+1-240-599-4500

Web site: <http://www.vandapharma.com>

(VNDA)

CO: Vanda Pharmaceuticals Inc.