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 16, 2010

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:

- 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 2.02. Results of Operations and Financial Condition.

On February 16, 2010, Vanda Pharmaceuticals Inc. issued a press release relating to its results of operations and financial condition for the fourth quarter and fiscal year ended December 31, 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

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated February 16, 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 and Treasurer

Dated: February 16, 2010



Company Contact:

Stephanie R. Irish Acting Chief Financial Officer

Vanda Pharmaceuticals Inc. (240) 599-4500 stephanie.irish@vandapharma.com

Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2009 Results

ROCKVILLE, MD. — February 16, 2010 — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: <u>VNDA</u>), 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 fourth quarter and full year ended December 31, 2009.

Vanda reported a net loss of \$9.2 million for the fourth quarter of 2009, compared to \$7.7 million for the third quarter of 2009 and \$7.5 million for the fourth quarter of 2008. Total revenue for the fourth quarter of 2009 was \$4.5 million, consisting of \$2.6 million in upfront licensing revenue and \$1.9 million in product revenue for inventory sold to Novartis Pharma AG (Novartis). The remaining \$197.4 million in deferred revenue relating to the \$200.0 million upfront payment received from Novartis pursuant to the Fanapt™ (iloperidone) license agreement will be recognized ratably (\$2.2 million per month) through May 2017. Total expenses for the fourth quarter of 2009 were \$13.8 million, compared to \$7.7 million for the third quarter of 2009 and \$7.7 million for the fourth quarter of 2008. Research and development (R&D) expenses for the fourth quarter of 2009 were \$2.3 million, compared to \$2.1 million for the third quarter of 2009 and \$3.6 million for the fourth quarter of 2008. For the full year of 2009, total expenses were \$40.5 million, compared to \$52.8 million for 2008. Total 2009 R&D expenses were \$13.9 million, compared to \$23.9 million during 2008.

As of December 31, 2009, Vanda's cash, cash equivalents, and marketable securities totaled approximately \$205.3 million. As of December 31, 2009, a total of approximately 27.6 million shares of Vanda common stock were outstanding. Net loss per common share for the fourth quarter of 2009 was \$0.34, compared to \$0.28 for the third quarter of 2009 and \$0.28 for the fourth quarter of 2008. For the full year of 2009, net loss per common share was \$1.33, compared to \$1.92 for the full year of 2008.

OPERATIONAL HIGHLIGHTS

During the fourth quarter of 2009, Vanda focused its efforts on the successful transition to Novartis of commercial, regulatory and manufacturing documents, materials and supplies relating to Fanapt TM . On January 11, 2010, Vanda announced that Novartis Pharmaceuticals

Corporation had launched FanaptTM in the U.S. Vanda has explored, and continues to evaluate, the regulatory path and commercial opportunity for FanaptTM outside of the U.S. and Canada.

Vanda also continued the clinical, regulatory and commercial evaluation of tasimelteon, its selective melatonin receptor agonist, during the fourth quarter of 2009. Compounds that bind selectively to melatonin receptors are candidates to treat sleep disorders, including Circadian Rhythm Sleep Disorders (CRSDs), and additionally are believed to offer potential benefits in mood disorders. Tasimelteon is currently in Phase III stage of development for the treatment of sleep disorders and CRSDs and is ready for Phase II trials for the treatment of depression. On January 19, 2010, the U.S. Food and Drug Administration (FDA) granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Sleep/Wake Disorder in blind persons. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. As Vanda continues to explore the path to a New Drug Application (NDA) for tasimelteon, the orphan drug designation in Non-24 Hour Sleep/Wake Disorder has the potential to strengthen the tasimelteon program by offering clinical development and commercialization benefits.

FINANCIAL DETAILS

- Operating Expenses. R&D expenses of \$2.3 million for the fourth quarter of 2009 consisted primarily of \$0.9 million of salaries and benefits, \$0.5 million of non-cash stock based compensation costs for R&D personnel, \$0.3 million in consulting fees and \$0.2 million for an on-going carcinogenicity study. This compares to \$2.1 million for the third quarter of 2009 and \$3.6 million for the fourth quarter of 2008. The increase in R&D expenses in the fourth quarter of 2009 relative to the third quarter of 2009 is primarily due to 2009 employee bonus expense. The decrease in R&D expenses in the fourth quarter of 2009 relative to the fourth quarter of 2008 is primarily due to the regulatory consulting fees relating to Fanapt™ accrued in the fourth quarter of 2008. For the full year of 2009, total R&D expenses were \$13.9 million, compared to \$23.9 million for 2008. Lower R&D expenses resulted from the lower clinical trial costs and related manufacturing costs incurred in 2009.
- General and administrative (G&A) expenses of \$9.2 million for the fourth quarter of 2009 consisted primarily of \$1.3 million of salaries and benefits and \$1.9 million of non-cash stock based compensation costs for G&A personnel, as well as \$1.2 million of legal fees and \$3.7 million of consulting fees and financial advisors fees primarily relating to the transaction with Novartis, and \$0.2 million of insurance costs. This compares to \$5.3 million for the third quarter of 2009 and \$4.1 million for the fourth quarter of 2008. The increase in G&A expenses in the fourth quarter of 2009 relative to the third quarter of 2009 and the fourth quarter of 2008 is primarily due to an increase in legal and consulting fees and financial advisor fees accrued in the fourth quarter of 2009 relating to the transaction with Novartis. For the full year of 2009, total G&A expenses were \$23.7 million, compared to \$28.9 million for 2008. The year-over-year decrease in G&A expenses is primarily due to decreased commercial and marketing expenses relating to Fanapt™.
- Employee stock-based compensation expense recorded in the fourth quarter of 2009 totaled \$2.4 million. Of these non-cash charges, \$0.5 million was recorded as R&D

expense and \$1.9 million was recorded as G&A expense. For the third quarter of 2009 and the fourth quarter of 2008, total stock-based compensation expense was \$3.3 million and \$0.7 million, respectively. The decrease in stock-based compensation expense in the fourth quarter of 2009 relative to the third quarter of 2009 is the result of the full vesting of non-qualified options issued at a higher fair market value. The increase in stock-based compensation expense in the fourth quarter of 2009 relative to the fourth quarter of 2008 is primarily due to a lower stock-based compensation expense resulting from the workforce reduction in the fourth quarter of 2008. For the full year of 2009, total stock-based compensation was \$10.8 million, compared to \$13.4 million for 2008.

- Cash and marketable securities increased by \$184.6 million during the fourth quarter of 2009. Changes included \$9.2 million of net losses, the payment of the \$5.0 million balance due to Novartis for the milestone payment relating to the FDA's approval of the NDA for Fanapt™ and increases in other working capital of \$1.9 million, offset by increases in the deferred revenue of \$197.4 million, \$3.0 million in non-cash depreciation, amortization, and stock-based compensation expense and \$0.3 million in proceeds from the exercise of employee stock options.
- Vanda's cash, cash equivalents and marketable securities as of December 31, 2009 totaled approximately \$205.3 million, compared to approximately \$46.5 million as of December 31, 2008.
- Net loss for the fourth quarter of 2009 was \$9.2 million, compared to a net loss of \$7.7 million for the third quarter of 2009 and a net loss of \$7.5 million for the fourth quarter of 2008. For the full year of 2009, net loss was \$35.9 million, compared to \$51.1 million for the full year of 2008.
- Net loss per common share for the fourth quarter of 2009 was \$0.34, compared to \$0.28 for the third quarter of 2009 and \$0.28 for the fourth quarter of 2008. For the full year of 2009, net loss per common share was \$1.33, compared to \$1.92 for the full year of 2008.

FINANCIAL GUIDANCE

Vanda's primary objective over the next quarter is to conserve cash while supporting the Fanapt™ launch. In addition, the Company intends to engage in discussions with several foreign regulatory agencies to review their filing requirements with respect to Fanapt™. Vanda also plans to continue the clinical, regulatory and commercial evaluation of tasimelteon. Although Vanda incurred transaction-related costs of approximately \$6.0 million in the fourth quarter of 2009, which included financial advisor fees, consulting fees, legal expenses and employee bonuses, and \$2.0 million in Fanapt™ inventory costs, Vanda's fixed overhead costs are expected to be approximately \$10.0 million to \$12.0 million annually. Vanda will recognize revenue of \$26.8 million in 2010 for the amortization of the deferred upfront payment received from Novartis. The forecasted royalty revenue and sales milestones based on sales of Fanapt™ by Novartis can not be determined at this time. Vanda expects to receive approximately \$7.7 million from Novartis for Fanapt™ inventory, of which \$2.0 million was recorded as a receivable at year-end.

Vanda is currently working with its tax advisors to determine its tax liability relating to the receipt of the \$200.0 million upfront payment from Novartis in late 2009. Generally, under the Internal Revenue Code, an accrual basis taxpayer is required to include in taxable income certain cash

payments in the year received. Revenue Procedure 2004-34, however, allows taxpayers a limited deferral beyond the taxable year of receipt for certain advance payments. For federal income tax purposes, Vanda may avail itself of the provisions of this Revenue Procedure to defer recognition of income on the upfront payment from Novartis. As a result, only a portion of the \$200.0 million upfront payment from Novartis that was received in 2009 is expected to be included in taxable income for the tax year ended December 31, 2009. Any of the income from the \$200.0 million payment that was not recognized in 2009 will be recognized in taxable income for the year ending December 31, 2010 and is expected to create income tax liabilities for the Company. The timing of the payment of the income taxes due is largely dependent upon when the income is recognized for financial statement purposes, as well as the Company's ability to utilize its carry forward tax attributes in offsetting the income recognized from the receipt of the \$200.0 million upfront payment.

As of December 31, 2008, Vanda has approximately \$123.7 million of net operating loss carry forwards incurred since 2003, which potentially may be used in part to offset future taxable income and thereby reduce Vanda's U.S. federal income taxes that would otherwise be payable. Section 382 of the Internal Revenue Code (Section 382), imposes an annual limit on the ability of a corporation that undergoes an "ownership change" to use its net operating loss carry forwards to reduce its tax liability. As a result of certain changes in Vanda's shareholder base, Vanda's ability to utilize its net operating losses to offset future taxable income in any particular year may be limited pursuant to Section 382.

CONFERENCE CALL

Vanda has scheduled a conference call for today, Tuesday, February 16, 2010, at 9:30 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 1-866-730-5762 (domestic) and 1-857-350-1586 (international) prior to the 9:30 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos (participant passcode 75344663). A replay of the call will be available Tuesday, February 16, 2010, at 12:30 PM ET and will be accessible until Tuesday, February 23, 2010, 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 85072095. The conference call will be broadcast simultaneously on the 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 March 18, 2010.

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. 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 FanaptTM 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 September 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended		Year Ended	
	December 31, 2009	December 31, 2008	December 31, 2009	December 31, 2008
Revenue from licensing agreement	\$ 2,568,807	\$ —	\$ 2,568,807	\$ —
Product revenue	1,978,937	_	1,978,937	_
Total revenue	4,547,744	_	4,547,744	_
Operating expenses:				
Cost of sales — licensing agreement	376,792	_	982,935	_
Cost of sales — product	1,914,690	_	1,914,690	_
Research and development	2,253,041	3,559,543	13,873,961	23,935,541
General and administrative	9,245,317	4,095,118	23,724,101	28,909,580
Total operating expenses	13,789,840	7,654,661	40,495,687	52,845,121
Loss from operations	(9,242,096)	(7,654,661)	(35,947,943)	(52,845,121)
Interest income	4,706	150,642	89,097	1,780,880
Net loss	\$ (9,237,390)	\$ (7,504,019)	\$ (35,858,846)	\$(51,064,241)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.34)	\$ (0.28)	\$ (1.33)	\$ (1.92)
	* (3.2)	<u> </u>	<u> </u>	4 (12)
Shares used in calculation of basic and diluted net loss per share				
attributable to common stockholders	27,286,667	26,652,187	27,015,271	26,650,126
	6			

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	<u>December 31, 2009</u>	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 205,295,488	\$ 39,079,304
Marketable securities	-	7,378,798
Accounts receivable	3,163,898	_
Inventory	2,398,517	_
Prepaid expenses, deposits and other current assets	2,092,581	1,287,400
Total current assets	212,950,484	47,745,502
Property and equipment, net	1,316,302	1,758,111
Restricted cash	430,230	430,230
Intangible asset, net	11,017,065	_
Total assets	\$ 225,714,081	\$ 49,933,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,423,877	\$ 512,382
Accrued expenses	2,321,301	2,898,417
Deferred revenues, current portion	26,788,991	_
Total current liabilities	31,534,169	3,410,799
Long-term liabilities:		
Deferred rent	506,852	502,770
Deferred revenues, noncurrent portion	170,642,202	_
Total liabilities	202,683,223	3,913,569
Stockholders' equity:		
Common stock	27,569	26,653
Additional paid-in capital	283,836,642	270,988,157
Accumulated other comprehensive loss	· · · · · · · · · · · · · · · · · · ·	(20,029)
Accumulated deficit	(260,833,353)	(224,974,507)
Total stockholders' equity	23,030,858	46,020,274
Total liabilities and stockholders' equity	\$ 225,714,081	\$ 49,933,843
7		

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Year Ended	
	December 31, 2009	December 31, 2008
Cash flows from operating activities:		
Net loss	\$ (35,858,846)	\$(51,064,241)
Adjustments to reconcile net loss to net cash used in operating activities:		, , , ,
Depreciation and amortization	441,809	530,805
Employee and non-employee stock-based compensation	11,230,227	13,387,789
Loss on disposal of assets	_	(174)
Amortization of discounts and premiums on marketable securities	138,095	(235,162)
Amortization of intangible assets	982,935	
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(805,181)	495,200
Accounts receivable	(3,163,898)	_
Deposits	<u> </u>	150,000
Inventory	(2,398,517)	_
Accounts payable	1,911,495	(2,475,697)
Accrued expenses	(577,116)	(6,892,577)
Deferred rent	4,082	148,728
Deferred revenue	197,431,193	_
Net cash provided by (used in) operating activities	169,336,278	(45,955,329)
Cash flows from investing activities:		
Acquisition of intangible asset	(12,000,000)	_
Purchases of property and equipment	` _ ´	(943,659)
Purchases of marketable securities	(11,365,815)	(14,786,080)
Proceeds from sales of marketable securities	126,547	11,258,094
Maturities of marketable securities	18,500,000	47,560,000
Net cash provided by (used in) investing activities	(4,739,268)	43,088,355
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,619,174	_
Net cash provided by financing activities	1,619,174	
Effect of foreign currency	_	16,745
Net change in cash and cash equivalents	166,216,184	(2,850,229)
		· · ·
Cash and cash equivalents, beginning of period	39,079,304	41,929,533
Cash and cash equivalents, end of period	\$205,295,488	\$ 39,079,304
8		

SOURCE Vanda Pharmaceuticals Inc.

2/16/2010

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.