# **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): April 29, 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 April 29, 2009, Vanda Pharmaceuticals Inc. issued a press release relating to its results of operations and financial condition for the first quarter ended March 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 April 29, 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: April 29, 2009



#### 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 First Quarter 2009 Results

**ROCKVILLE, MD.** — April 29, 2009 — Vanda Pharmaceuticals Inc. (NASDAQ: <u>VNDA</u>), a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates for central nervous system disorders, today announced financial and operational results for the first quarter ended March 31, 2009.

Vanda reported a net loss of \$6.5 million for the first quarter of 2009, compared to \$7.5 million for the fourth quarter of 2008. Total expenses for the first quarter of 2009 were \$6.6 million, compared to \$7.7 million for the fourth quarter of 2008. Research and development (R&D) expenses for the first quarter of 2009 were \$2.3 million, compared to \$3.6 million for the fourth quarter of 2008. The decrease in R&D expenses in the first quarter of 2009 relative to the fourth quarter of 2008 is primarily due to the decrease in regulatory consulting and other professional fees.

As of March 31, 2009, Vanda's cash, cash equivalents, and marketable securities totaled approximately \$42.6 million. As of March 31, 2009, a total of approximately 26.7 million shares of Vanda common stock were outstanding. Net loss per common share for the first quarter of 2009 was \$0.24, compared to \$0.28 for the fourth quarter of 2008.

#### **OPERATIONAL HIGHLIGHTS**

On November 6, 2008, Vanda submitted a Complete Response to the not approvable action letter that the Company received from the U.S. Food and Drug Administration (FDA) on July 25, 2008 regarding iloperidone. The FDA accepted the Complete Response for review and has set a new target action date of May 6, 2009. Pending a response from the FDA, Vanda is concentrating its efforts on the design and evaluation of clinical development options for tasimelteon, its compound for sleep and mood disorders, including Circadian Rhythm Sleep Disorders.

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#### **FINANCIAL DETAILS**

Operating Expenses. First quarter 2009 R&D expenses of \$2.3 million, consisted primarily of \$0.5 million of salaries and benefits and \$0.2 million of non-cash stock based compensation costs for R&D personnel, as well as \$0.8 million of regulatory consultant fees, and \$0.2 million of pre-clinical work. This compares to \$3.6 million for the fourth quarter of 2008 and \$11.1 million for the first quarter of 2008. The decrease in R&D expenses in the first quarter of 2009 relative to the fourth quarter of 2008 is primarily due to the decrease in regulatory consulting and other professional fees related to iloperidone. The decrease in R&D expenses in the first quarter of 2009 relative to the first quarter of 2008 is primarily due to the completion in the second quarter of 2008 of the Phase III clinical trial for tasimelteon in chronic primary insomnia.

General and administrative (G&A) expenses of \$4.2 million for the first quarter of 2009 consisted primarily of \$0.5 million of salaries and benefits and \$2.1 million of non-cash stock based compensation costs for G&A personnel, as well as \$0.7 million of legal fees, and \$0.2 million of insurance costs. This compares to \$4.1 million for the fourth quarter of 2008 and \$9.0 million for the first quarter of 2008. The increase in G&A expenses in the first quarter of 2009 relative to the fourth quarter of 2008 is primarily due to an increase in legal and professional fees offset by a decrease in stock-based compensation costs. The decrease in G&A expenses in the first quarter of 2009 relative to the first quarter of 2008 is primarily due to lower stock-based compensation and commercial expenses.

Employee stock-based compensation expense recorded in the first quarter of 2009 totaled \$2.3 million. Of these non-cash charges, \$0.2 million was recorded as R&D expense and \$2.1 million was recorded as G&A expense. For the fourth quarter of 2008 and the first quarter of 2008, total stock-based compensation expense was \$0.7 million and \$5.1 million, respectively. The increase in stock-based compensation expense in the first quarter of 2009 relative to the fourth quarter of 2008 is the result of the fourth quarter expense encompassing the net effect of stock-based compensation for the period for existing employees, reduced by the reversal of stock-based compensation charges resulting from the cancellation of unvested options in connection with the workforce reduction which occurred in the fourth quarter of 2008. The decrease in stock-based compensation expense in the first quarter of 2009 relative to the first quarter of 2008 is primarily due to no options being granted in the first quarter of 2009.

- Cash and marketable securities decreased by \$3.8 million during the first quarter of 2009. Changes included \$6.5 million of net losses offset by increases in accrued expenses and accounts payable of \$0.1 million, decreases in prepaid expenses of \$0.2 million and \$2.4 million in non-cash depreciation, amortization, and stock-based compensation expense.
- Vanda's cash, cash equivalents and marketable securities as of March 31, 2009 totaled approximately \$42.6 million, compared to approximately \$46.5 million as of December 31, 2008.
- Net loss for the first quarter of 2009 was \$6.5 million, compared to a net loss of \$7.5 million for the fourth quarter of 2008 and a net loss of \$19.2 million for the first quarter of 2008.
- Net loss per common share for the first quarter of 2009 was \$0.24, compared to \$0.28 for the fourth quarter of 2008 and \$0.72 for the first quarter of 2008.

#### **FINANCIAL GUIDANCE**

Vanda will update its financial guidance following the decision by the FDA regarding the New Drug Application for iloperidone.

#### ABOUT VANDA PHARMACEUTICALS INC.:

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates 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 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: delays in the completion of Vanda's clinical trials; a failure of Vanda's product candidates to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's product candidates in the marketplace, or a failure to become or remain profitable. Vanda's inability to obtain the capital necessary to fund its research and development activities; Vanda's failure to identify or obtain rights to new product candidates; 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 I, Item 1A) of Vanda's annual report on Form 10-K/A for the fiscal year ended December 31, 2008 (File No. 001-34186). In addition to the risks described above and in Part I, Item 1A of Vanda's annual report on Form 10-K/A, 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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# VANDA PHARMACEUTICALS INC. (A Development Stage Enterprise) CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended	
	March 31, 2009	March 31, 2008
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	2,333,344	11,102,665
General and administrative	4,224,031	8,959,214
Total operating expenses	6,557,375	20,061,879
Loss from operations	(6,557,375)	(20,061,879)
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Interest income	53,387	865,750
Total other income, net	53,387	865,750
Net loss	\$ (6,503,988)	\$(19,196,129)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.24)	\$ (0.72)
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Shares used in calculation of basic and diluted net loss per share attributable to common		
stockholders	26,653,478	26,648,344
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## VANDA PHARMACEUTICALS INC. (A Development Stage Enterprise) CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 33,833,465	\$ 39,079,304
Marketable securities	8,810,919	7,378,798
Prepaid expenses, deposits and other current assets	<u>1,118,672</u>	1,287,400
Total current assets	43,763,056	47,745,502
Property and equipment, net	1,635,316	1,758,111
Restricted cash	430,230	430,230
Total assets	\$ 45,828,602	\$ 49,933,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,415,384	\$ 512,382
Accrued expenses	2,065,219	2,898,417
Total current liabilities	3,480,603	3,410,799
Long-term liabilities:		
Deferred rent	503,791	502,770
Total liabilities	3,984,394	3,913,569
Stockholders' equity:	<del></del>	
Common stock	26,653	26,653
Additional paid-in capital	273,296,804	270,988,157
Accumulated other comprehensive loss	(754)	(20,029)
Deficit accumulated during the development stage	(231,478,495)	(224,974,507)
Total stockholders' equity	41,844,208	46,020,274
Total liabilities and stockholders' equity	\$ 45,828,602	\$ 49,933,843
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# VANDA PHARMACEUTICALS INC. (A Development Stage Enterprise) CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Three Mo	nths Ended
	March 31, 2009	March 31, 2008
Cash flows from operating activities:		
Net loss	\$ (6,503,988)	\$(19,196,129)
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	122,795	122,629
Stock-based compensation	2,308,647	5,105,714
Loss on disposal of assets	_	610
Amortization of net discounts on short-term investments	38,263	(162,519)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	168,728	606,421
Accounts payable	903,002	(1,355,101)
Accrued expenses	(833,198)	(1,299,209)
Other liabilities	1,021	68,365
Net cash used in operating activities	(3,794,730)	(16,109,219)
Cash flows from investing activities:		
Purchases of property and equipment		(186,442)
Purchases of marketable securities	(5,077,656)	(1,485,150)
Proceeds from sales of marketable securities	126,547	2,790,026
Maturities of marketable securities	3,500,000	29,060,000
Net cash provided by (used in) investing activities		30,178,434
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Cash flows from financing activities:		
Net cash provided by financing activities	<u></u>	<u></u>
Effect of foreign currency translation	_	16,745
	(5.0.45.000)	11.005.000
Net change in cash and cash equivalents	(5,245,839)	14,085,960
Cash and cash equivalents, beginning of period	39,079,304	41,929,533
Cash and cash equivalents, end of period	<u>\$33,833,465</u>	\$ 56,015,493
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SOURCE Vanda Pharmaceuticals Inc.

04/29/2009

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

(VNDA)

CO: Vanda Pharmaceuticals Inc.

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