# **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): May 5, 2011

# VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

#### **Delaware**

(State or other jurisdiction of incorporation)

001-34186 (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 May 5, 2011, Vanda Pharmaceuticals Inc. (the "Company" or "Vanda") issued a press release and held a conference call regarding its results of operations and financial condition for the quarter ended March 31, 2011. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Various statements made during the conference call were "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," or the negative of these terms 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 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, product candidates or partnered products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or product candidates or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's products, product candidates or partnered 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 additional research and development activities; Vanda's failure to identify or obtain rights to new products or product candidates; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda's ability to utilize some or all of its prior net operating losses and research and development credits; 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 or product candidates under its license and sublicense agreements and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, which is on file with the SEC and available on the SEC website at www.sec.gov. Additional information will also be set forth in those sections of Vanda's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, which will be filed with the SEC in the second quarter of 2011. In addition to the risks described above and in Vanda's Annual Report on Form 10-K and Quarterly Reports 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 conveyed on the conference call will be provided only as of the date of the call, and the Company undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the call after the date thereof, whether as a result of new information, future events, or otherwise.

The information in Item 2.02 of this Current Report on 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 May 5, 2011.	

# **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/ James Kelly

Name: James Kelly

Title: Chief Financial Officer

Dated: May 9, 2011



### **Company Contact:**

Cristina Murphy
Communications Manager
Vanda Pharmaceuticals Inc.
(240) 599-4500
cristina.murphy@vandapharma.com

### Vanda Pharmaceuticals Reports First Quarter 2011 Results

**ROCKVILLE, MD.** — May 5, 2011 — Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: <u>VNDA</u>), a biopharmaceutical company focused on the development and commercialization of products for central nervous system disorders, today announced financial and operational results for the first quarter ended March 31, 2011.

"We are very excited about the significant progress we have made to date in 2011" said Mihael H. Polymeropoulos, M.D., President and Chief Executive Officer. "Our first product, Fanapt®, which is marketed in the U.S. for the treatment of schizophrenia has now entered a Phase I study to evaluate the safety and pharmacokinetic profiles of two different long-acting formulations in patients with schizophrenia. In addition, we have expanded the tasimelteon clinical program with a Phase IIb/III Study in Major Depression that will begin in the second half of 2011."

# Key Highlights:

- Vanda recorded first quarter 2011 revenue of \$7.5 million including royalties of \$0.9 million. Fanapt® prescriptions, as reported by IMS, reached 25,000 in the first quarter of 2011.
- Fanapt® long-acting injectable (depot) formulation advanced into clinical studies.
- European filing for oral Fanapt® is targeted for the second half of 2011.
- Tasimelteon program expanded to include a Phase IIb/III study in patients with Major Depressive Disorder. Study expected to begin in the second half of 2011.
- The European Commission (EC) granted orphan drug designation for tasimelteon for Non-24-Hour Sleep/Wake Disorder (N24HSWD.)
- Top-line efficacy results for tasimelteon for N24HSWD are expected in mid 2012; NDA submission planned for the first half of 2013.

Page 1 of 8

# FIRST QUARTER 2011 REPORTED RESULTS

Total revenues for the first quarter of 2011 were \$7.5 million, compared to \$12.4 million for the same period in 2010. First quarter 2011 revenues included \$0.9 million related to Fanapt® royalties received from Novartis as compared to \$2.1 million for the first quarter of 2010. The higher first quarter 2010 royalty revenue was the result of initial wholesaler stocking at launch. First quarter 2010 revenues also included one-time product sales to Novartis of \$3.7 million. Total operating expenses for the first quarter of 2011 were \$7.5 million, compared to \$6.3 million for the first quarter of 2010. The primary driver of the higher expenses in the first quarter of 2011 was the ongoing support of the tasimelteon N24HSWD clinical studies.

Net income was \$0.1 million for the first quarter of 2011, compared to \$0.5 million for the first quarter of 2010. Basic and diluted earnings per share for the first quarter of 2011 were \$0.00, compared to \$0.02 per share for the first quarter of 2010.

# First Quarter 2011 Key Financial Figures1

	Three Months Ended			
(in thousands, except per share amounts)	March 31 2011	December 31 2010	Change (\$)	Change (%)
Total revenues	\$ 7,501	\$ 7,752	\$ (251)	-3%
Research & development expenses	4,267	3,822	445	12%
General & administrative expenses	2,858	2,762	96	3%
Non-cash stock-based compensation <sup>2</sup>	1,604	1,335	269	20%
Net income (loss) before tax provision	142	933	(791)	-85%
Tax provision (benefit)	6	(1,266)	1,272	NA
Net income (loss)	136	2,200	(2,064)	-94%
Diluted net income (loss) per share	\$ 0.00	\$ 0.08	\$ (0.08)	-100%

#### Select Cash Flow Data1

	Three Mor	nths Ended
(In thousands)	March 31 2011	March 31 2010
Net cash provided by (used in)		
Operating activities	(3,264)	(4,826)
Investing activities	13,225	(32,457)
Financing activities		1,933
Net change in cash and cash equivalents	\$ 9,961	\$ (35,350)

# Select Balance Sheet Data<sup>1</sup>

	March 31	December 31	March 31
(in thousands)		2010	2010
Total cash and marketable securities	\$ 194,555	\$ 198,037	\$202,424

<sup>(1)</sup> Unaudited

<sup>(2)</sup> Non-cash stock-based compensation is allocated to both Research & development and General & administrative expenses.

# **OPERATIONAL HIGHLIGHTS**

First quarter 2011 sales of Fanapt® were reported by Novartis to be \$9.0 million. Fanapt® prescriptions, as reported by IMS, reached 25,000 in the first quarter of 2011.

Novartis initiated a clinical study for the once a month injectable depot formulation of Fanapt<sup>®</sup> in April 2011. This is a Phase I study that will evaluate the safety and pharmacokinetic profiles of two different long-acting formulations of Fanapt<sup>®</sup> in patients with schizophrenia. A long-acting injectable formulation could offer a potential new option for patients with schizophrenia who might benefit from less frequent dosing compared to an oral medication.

Vanda expects to file for European regulatory approval of oral Fanapt® in the second half of 2011. This continues the effort to expand the availability of Fanapt® to markets outside the U.S. and Canada.

On March 31, 2011, Vanda announced plans to evaluate tasimelteon in Major Depressive Disorder. There is considerable evidence that suggests circadian rhythm disturbances are important in the pathophysiology of mood disorders. Treatment with tasimelteon would represent a novel and differentiated approach to assisting the millions of patients who suffer from the symptoms of major depression. A Phase IIb/III clinical trial will examine safety and efficacy of tasimelteon versus placebo and is expected to begin during the second half of 2011. The study will include an 8-week treatment period and an optional openlabel extension.

Enrollment is ongoing in tasimelteon studies VP-VEC-162-3201 (efficacy) and VP-VEC-162-3202 (safety) in the treatment of N24HSWD in totally blind individuals. Top line efficacy results are expected in mid 2012 and an NDA submission is planned for the first half of 2013.

On March 8, 2011, tasimelteon was granted orphan drug designation by the European Commission (EC) for the treatment of N24HSWD in totally blind individuals. Orphan designation for a medicinal product by the EC provides benefits that can take a variety of forms including tax incentives, protocol assistance, eligibility for grants and initiatives supporting research and development related to this orphan indication, reduction of marketing application fees and annual fees for qualifying companies, and potential marketing exclusivity for up to 10 years in the European Union.

#### **REVISED FULL YEAR 2011 FINANCIAL GUIDANCE**

- General and administrative expenses are expected to be between \$10.0 and \$12.0 million.
- Research and development expenses are expected to be between \$30.0 and \$34.0 million.
- Total U.S. GAAP operating expenses are expected to be between \$41.0 and \$47.0 million. This includes \$1.5 million related to amortization of an intangible asset and \$5.0 to \$6.0 million of stock-based compensation.

# **CONFERENCE CALL**

Vanda has scheduled a conference call for today, Thursday, May 5, 2011, at 10:00 AM ET. During the call, Mihael H. Polymeropoulos, M.D., President and CEO, and James P. Kelly, Senior Vice President and Chief Financial Officer, will discuss the first quarter 2011 results and other corporate activities. Investors can call 1-866-383-7998 (domestic) and 1-617-597-5329 (international) prior to the 10:00 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos (participant passcode 44118664). A replay of the call will be available beginning Thursday, May 5, 2011 at 1:00 PM ET and will be accessible until Thursday, May 12, 2011, 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 73214212.

The conference call will be broadcast simultaneously on Vanda's website, http://www.vandapharma.com. Investors should click on the Investor Relations tab and are advised to go to the website at least 15 minutes early to register, download, and install any necessary software or presentations. The call will also be archived on Vanda's website for a period of 30 days, through June 3, 2011.

#### ABOUT VANDA PHARMACEUTICALS INC.:

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for central nervous system disorders. For more on Vanda, 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," "would," and "could," or the negative of these terms 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 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, product candidates or partnered products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's products, product candidates or partnered 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 additional research and development activities; Vanda's failure to identify or obtain rights to new products or product candidates; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; limitations on Vanda's ability to utilize some or all of its prior net operating losses and research and development credits; 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 or product candidates under its license and sublicense agreements and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2010 which is on file with the SEC and available on the SEC's website at <a href="www.sec.gov">www.sec.gov</a>. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports 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.

####

Page 5 of 8

# VANDA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

		Three Months Ended		
	M	arch 31, 2011		rch 31, 2010
(In thousands, except for per share amounts)  Revenues:		2011		2010
Licensing agreement	\$	6,606	\$	6,606
Royalty revenue		895		2,067
Product sales		_		3,748
Total revenues		7,501		12,421
Operating expenses:				
Cost of sales — product		_		1,375
Research and development		4,267		2,041
General and administrative		2,858		2,489
Intangible asset amortization		369		369
Total operating expenses		7,494		6,274
		· · · · · · · · · · · · · · · · · · ·		
Income from operations		7		6,147
Other income:				
Interest income		135		47
Total other income		135		47
Income before income tax provision		142		6,194
Tax provision		6		5,665
Net income	\$	136	\$	529
Net income per share:				
Basic and diluted	\$	0.00	\$	0.02
Shares used in calculation of net income per share:				
Basic	28	101,418	27,	704,418
Diluted		936,835		318,754
2 Auteu		323,000		010,70 F

# VANDA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(In thousands)	March 31, 201		December 31, 2010	
ASSETS				
Current assets:				
Cash and cash equivalents	\$	52,520	\$	42,559
Marketable securities		142,035		155,478
Accounts receivable		895		511
Prepaid expenses, deposits and other current assets		1,619		1,843
Deferred tax, current		182		182
Total current assets		197,251		200,573
Property and equipment, net		860		937
Intangible asset, net		9,153		9,522
Deferred tax, non-current		1,639		1,639
Restricted cash		430		430
Total assets	\$	209,333	\$	213,101
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	834	\$	648
Accrued liabilities		2,141		1,324
Accrued income taxes		2,272		2,266
Deferred revenue, current		26,789		26,789
Total current liabilities		32,036		31,027
Long-term liabilities:				
Deferred rent		482		490
Deferred revenue, non-current		137,247		143,853
Total liabilities		169,765		175,370
Stockholders' equity:				
Common stock		28		28
Additional paid-in capital		292,946		291,342
Accumulated other comprehensive income		99		2
Accumulated deficit		(253,505)		(253,641)
Total stockholders' equity		39,568		37,731
Total liabilities and stockholders' equity	\$	209,333	\$	213,101
Page 7 of 8				
1 age / 01 0				

SOURCE Vanda Pharmaceuticals Inc.

 $CONTACT: Cristina\ Murphy, Communications\ Manager,\ of\ Vanda\ Pharmaceuticals\ Inc.,\ +1-240-599-4500$ 

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

(VNDA)

CO: Vanda Pharmaceuticals Inc.

Page 8 of 8