# 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 14, 2012

### 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)

	the 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 isions:
	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))
П	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 14, 2012, Vanda Pharmaceuticals Inc. (the "Company" or "Vanda") issued a press release and is holding a conference call regarding its results of operations and financial condition for the fourth quarter and year ended December 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 to be made during the conference call are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "project," "intend," "plan," "target," "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 and its partners' 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 revenues, costs, expenses and liabilities; 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which will be filed with the SEC in the first quarter of 2012. 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 February 14, 2012.

#### **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: February 14, 2012



#### **Company Contact:**

Cristina Murphy Senior Communications Manager Vanda Pharmaceuticals Inc. (240) 599-4500

cristina.murphy@vandapharma.com

#### Vanda Pharmaceuticals Reports Fourth Quarter 2011 and Full Year 2011 Results

**ROCKVILLE, MD.** – February 14, 2012 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: <u>VNDA</u>), a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders, today announced financial and operational results for the fourth quarter and twelve months ended December 31, 2011.

#### Key Highlights:

- Initial clinical data in the RESET study revealed potential of tasimelteon to reset the body clock in Non-24-Hour Sleep-Wake Disorder (Non-24-Hour Disorder).
- The tasimelteon Non-24-Hour Disorder program continues to advance towards a projected mid-2013 New Drug Application (NDA) filing with the U.S. Food and Drug Administration (FDA). Vanda expects to complete the two Phase III efficacy studies, SET and RESET, by the end of 2012.
- The tasimelteon MAGELLAN Phase IIb/III efficacy study for Major Depressive Disorder (MDD) is ongoing and Vanda expects to report top-line results in the first half of 2013.
- Vanda recorded fourth quarter 2011 revenue of \$8.4 million including royalties of \$1.6 million. Full year 2011 Fanapt® prescriptions, as reported by IMS, exceeded 120,000, compared to approximately 55,000 for 2010.

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#### **FULL YEAR 2011 REPORTED RESULTS**

Total revenues for the full year 2011 were \$31.3 million, compared to \$35.7 million for 2010. Full year 2011 revenues included \$4.5 million in Fanapt® royalties received from Novartis, as compared to \$3.1 million for the prior year. Both 2011 and 2010 revenues include \$26.8 million recognized from the \$200.0 million upfront payment previously received from Novartis for Fanapt® U.S. and Canadian rights. 2010 full year revenues also included \$5.8 million in product sales to Novartis and grant revenue.

Total operating expenses for 2011 were \$42.0 million, compared to \$26.9 million for 2010. The primary driver of the higher expenses in 2011 was the ongoing support of the tasimelteon Non-24-Hour Disorder and MDD clinical studies.

Vanda recorded a net loss of \$9.8 million for 2011, compared to net income of \$7.2 million for 2010. Diluted net loss per share for 2011 was \$0.35, compared to diluted net income per share of \$0.25 for 2010.

Vanda's cash, cash equivalents and marketable securities as of December 31, 2011 totaled \$167.9 million.

#### **FOURTH QUARTER 2011 REPORTED RESULTS**

Total revenues for the fourth quarter of 2011 were \$8.4 million, compared to \$7.8 million for 2010. Fourth quarter 2011 revenues included \$1.6 million in Fanapt® royalties received from Novartis as compared to royalties of \$0.5 million for the fourth quarter of 2010.

Total operating expenses for the fourth quarter of 2011 were \$14.3 million, compared to \$7.0 million for the fourth quarter of 2010. The primary driver of the higher expenses in the fourth quarter of 2011 was the initiation and ongoing support of the tasimelteon Non-24-Hour Disorder and MDD clinical studies.

Vanda recorded a net loss of \$5.5 million for the fourth quarter of 2011, compared to net income of \$2.2 million for the fourth quarter of 2010. Diluted net loss per share for the fourth quarter of 2011 was \$0.20, compared to diluted net income of \$0.08 per share for the fourth quarter of 2010.

#### Full Year December 31, 2011 Key Financial Figures<sup>1</sup>

	Twelve Months Ended			
(in thousands, except per share amounts)	December 31 2011	December 31 2010	Change (\$)	Change (%)
Total revenues	\$ 31,270	\$ 35,709	\$ (4,439)	-12%
Research & development expenses	28,996	12,338	16,658	135%
General & administrative expenses	11,486	10,147	1,339	13%
Non-cash stock-based compensation <sup>2</sup>	5,501	4,981	520	10%
Income (loss) before tax provision	(10,246)	9,269	(19,515)	-211%
Tax provision (benefit)	(444)	2,077	(2,521)	-121%
Net income (loss)	(9,802)	7,192	(16,994)	-236%
Diluted net income (loss) per share	\$ (0.35)	\$ 0.25	\$ (0.60)	-240%

#### Fourth Quarter 2011 Key Financial Figures<sup>1</sup>

	Three Months Ended				
(in thousands, except per share amounts)	December 31 2011	September 30 2011	Change (\$)	Change (%)	
Total revenues	\$ 8,370	\$ 7,969	\$ 401	5%	
Research & development expenses	10,556	8,174	2,382	29%	
General & administrative expenses	3,345	2,711	634	23%	
Non-cash stock-based compensation <sup>2</sup>	1,318	1,254	64	5%	
Loss before tax provision	(5,809)	(3,187)	(2,622)	-82%	
Tax benefit	(286)	(113)	(173)	-153%	
Net loss	(5,523)	(3,074)	(2,449)	-80%	
Diluted net loss per share	\$ (0.20)	\$ (0.11)	\$ (0.09)	-82%	

#### Select Cash Flow Data<sup>1</sup>

	Twelve Mor	Twelve Months Ended		
(in thousands)	December 31 2011	December 31 2010		
Net cash provided by (used in)				
Operating activities	(28,410)	(10,898)		
Investing activities	73,749	(155,622)		
Financing activities	25	3,784		
Net change in cash and cash equivalents	\$ 45,364	\$ (162,736)		

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

(in thousands)	December 31	September 30	December 31
		2011	2010
Total cash and marketable securities	\$ 167,896	\$ 180,459	\$ 198,037

- (1) Unaudited
- (2) Non-cash stock-based compensation is allocated to both Research & development and General & administrative expenses

#### **OPERATIONAL HIGHLIGHTS**

On January 26, 2012, Vanda announced that initial clinical data in the RESET study revealed the potential of tasimelteon to reset the body clock in Non-24-Hour Disorder. The tasimelteon Non-24-Hour Disorder program continues to advance towards a projected mid-2013 NDA filing with the FDA. Vanda is in continuing discussions with the FDA to confirm the path and requirements for this regulatory submission. Vanda expects to complete the two Phase III efficacy studies, SET and RESET, by the end of 2012.

The tasimelteon MAGELLAN efficacy study for MDD is ongoing and Vanda expects to report top-line results in the first half of 2013. This Phase IIb/III study in MDD was initiated in September 2011 and is expected to enroll 500 patients across approximately 40 sites.

Full year 2011 Fanapt® prescriptions, as reported by IMS, exceeded 120,000 compared to approximately 55,000 for 2010. Vanda has been informed that Novartis is continuing the Phase II development program for the long-acting injectable formulation of Fanapt®.

The review of Vanda's Marketing Authorization Application (MAA) for oral iloperidone tablets in the European Union is ongoing. The European Medicines Agency (EMA) has provided its standard 120-day list of questions and has granted Vanda a 3-month extension, through mid-May 2012, for Vanda to prepare its response. After further evaluation of the regulatory and commercial environment, Vanda has no current plans to pursue registration for Fanapt® in Singapore and Australia. Regulatory filings for market approval of Fanapt® by Vanda's commercial partners are under review in Israel, Mexico and Argentina.

#### **CONFERENCE CALL**

Vanda has scheduled a conference call for today, Tuesday, February 14, 2012, at 10:00 AM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2011 results and other corporate activities. Investors can call 866-271-0675 (domestic) and 617-213-8892 (international) and use passcode 76685033. A replay of the call will be available beginning Tuesday, February 14, 2012 at 12:00 PM ET and will be accessible until Tuesday, February 21, 2012, 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 37381299.

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 March 15, 2012.

#### **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.

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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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. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

		Three Months Ended			Twelve Months Ended				
(In thousands, except for per share amounts)		December 31 2011		December 31 2010		December 31 2011		December 31 2010	
Revenues:									
Licensing agreement	\$	6,752	\$	6,752	\$	26,789	\$	26,789	
Royalty revenue		1,618		511		4,481		3,141	
Product sales		_		_		_		5,290	
Grant revenue				489				489	
Total revenues		8,370		7,752		31,270		35,709	
Operating expenses:									
Cost of sales - product		_		_		_		2,891	
Research and development		10,556		3,822		28,996		12,338	
General and administrative		3,345		2,762		11,486		10,147	
Intangible asset amortization		377		377		1,495		1,495	
Total operating expenses		14,278		6,961		41,977		26,871	
Income (loss) from operations		(5,908)		791		(10,707)		8,838	
Other income:									
Interest income		99		142		461		431	
Total other income		99		142		461		431	
Income (loss) before income tax provision (benefit)		(5,809)		933		(10,246)		9,269	
Tax provision (benefit)		(286)		(1,266)		(444)		2,077	
Net income (loss)	\$	(5,523)	\$	2,199	\$	(9,802)	\$	7,192	
Net income (loss) per share:									
Basic	\$	(0.20)	\$	0.08	\$	(0.35)	\$	0.26	
Diluted	\$	(0.20)	\$	0.08	\$	(0.35)	\$	0.25	
Shares used in calculation of net income (loss) per share:									
Basic	28	,115,175	28	,038,074	28	3,106,831	27	,916,388	
Diluted	28	,115,175	28	,892,347	28	3,106,831	28	,534,617	

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

(In thousands)	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 87,923	\$ 42,559
Marketable securities, current	60,961	155,478
Accounts receivable	1,618	511
Prepaid expenses, deposits and other current assets	2,999	1,843
Deferred tax, current	<u> </u>	182
Total current assets	153,501	200,573
Marketable securities, non-current	19,012	_
Property and equipment, net	964	937
Other assets, non-current	84	_
Intangible asset, net	8,027	9,522
Deferred tax, non-current	<del>-</del>	1,639
Restricted cash	1,030	430
Total assets	\$ 182,618	\$ 213,101
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 996	\$ 648
Accrued liabilities	3,381	1,324
Accrued income taxes	<del>-</del>	2,266
Deferred rent, current	453	_
Deferred revenue, current	26,789	26,789
Total current liabilities	31,619	31,027
Non-current liabilities:		
Deferred rent, non-current	461	490
Deferred revenue, non-current	117,064	143,853
Total liabilities	149,144	175,370
Stockholders' equity:		
Common stock	28	28
Additional paid-in capital	296,868	291,342
Accumulated other comprehensive income	21	2
Accumulated deficit	(263,443)	(253,641)
Total stockholders' equity	33,474	37,731
Total liabilities and stockholders' equity	<u>\$ 182,618</u>	\$ 213,101

SOURCE Vanda Pharmaceuticals Inc.

COMPANY CONTACT:

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