## 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 8, 2014

### 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.)

2200 Pennsylvania Avenue NW Suite 300E Washington, DC 20037 (Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (202) 734-3400

 $\begin{tabular}{ll} \textbf{Not Applicable} \\ \textbf{(Former Name or Former Address, if Changed Since Last Report)} \\ \end{tabular}$ 

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 May 8, 2014, 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 quarter ended March 31, 2014. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are "forward-looking statements" under the securities laws, including, but not limited to, the Company's financial guidance for 2014. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "goal," "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: Vanda's ability to successfully commercialize HETLIOZ<sup>TM</sup> (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24") in the U.S.; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ™; Vanda's dependence on third-party manufacturers to manufacture HETLIOZ<sup>TM</sup> in sufficient quantities and quality; Vanda's limited sales and marketing infrastructure; the regulatory status of tasimelteon in Europe; Vanda's ability to obtain the capital necessary to fund its research and development or commercial activities; Vanda's loss of rights to develop and commercialize its products under its license and sublicense agreements; the failure to obtain, or any delay in obtaining, regulatory approval for Vanda's products, particularly HETLIOZ™ outside the U.S., or to comply with ongoing regulatory requirements; the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda's inability to successfully commercialize Fanapt® outside of the U.S. and Canada; a failure of Vanda's products to be demonstrably safe and effective; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; Vanda's failure to identify or obtain rights to new products; a loss of any of Vanda's key scientists or management personnel; limitations on Vanda's ability to utilize some or all of its prior net operating losses and orphan drug and research and development credits; the costs and effects of potential litigation; losses incurred from product liability claims made against Vanda 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, 2013 which is on file with the SEC and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, 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 Vanda 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 8, 2014.

#### **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 P. Kelly

Name: James P. Kelly

Title: Senior Vice President, Chief Financial Officer,

Secretary, and Treasurer

Dated: May 8, 2014



#### Vanda Pharmaceuticals Reports First Quarter 2014 Results

**WASHINGTON** – May 8, 2014 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), 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 first quarter ended March 31, 2014.

#### Key Highlights:

- On January 31, 2014, Vanda announced that the U.S. Food and Drug Administration (FDA) approved HETLIOZ™ (tasimelteon) 20mg capsules
  for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24). Non-24 affects the majority of totally blind individuals and it is estimated that
  approximately 80,000 Americans have the disorder.
- On April 21, 2014, Vanda launched HETLIOZ™ in the U.S. HETLIOZSolutions™ was also launched to support and facilitate the treatment of blind individuals in the U.S. living with Non-24.

#### FIRST QUARTER 2014 REPORTED RESULTS

Total revenues for the first quarter of 2014 were \$9.1 million, compared to \$8.1 million for the first quarter of 2013. First quarter 2014 revenues included \$1.7 million in Fanapt® royalties received from Novartis as compared to royalties of \$1.5 million for the first quarter of 2013. Licensing revenues recognized from the amortization of the \$200.0 million upfront payment received from Novartis for Fanapt® U.S. and Canadian rights were \$7.5 million for the first quarter 2014, compared to \$6.6 million for the first quarter of 2013. The higher amortization amount in the first quarter of 2014 resulted from a shortening of the expected patent life for Fanapt® in the U.S.

Total operating expenses for the first quarter of 2014 were \$35.7 million, compared to \$12.6 million for the first quarter of 2013. Selling, general and administrative expenses of \$27.9 million for the first quarter of 2014 were \$23.7 million higher than for the same period in 2013 and reflect the increased commercial activity in preparation for the launch of HETLIOZ™ in the U.S.

First quarter 2014 financial results include \$10.0 million for milestone payments associated with the FDA approval of the HETLIOZ<sup>TM</sup> New Drug Application. An \$8.0 million milestone payment was made to Bristol-Myers Squibb, which payment is treated as an intangible asset and will be amortized over the expected patent life of HETLIOZ<sup>TM</sup> in the U.S. A \$2.0 million regulatory consulting milestone payment was expensed to Research & development in the first quarter of 2014.

Vanda recorded a net loss of \$26.5 million for the first quarter of 2014, compared to a net loss of \$4.5 million for the first quarter of 2013. Diluted net loss per share for the first quarter of 2014 was \$0.79, compared to a diluted net loss per share of \$0.16 for the same period in 2013.

Cash, cash equivalents and marketable securities (Cash) were \$100.4 million as of March 31, 2014.

#### First Quarter 2014 Key Financial Figures(1) (2)

	Three Months Ended			
	March 31	December 31	C1 (A)	61 (0/)
(\$ in thousands, except per share amounts)	2014	2013	Change (\$)	Change (%)
Total revenues	\$ 9,143	\$ 8,783	\$ 360	4%
Research & development expenses	7,263	6,270	993	16%
Selling, general & administrative expenses	27,893	9,927	17,966	181%
Non-cash stock-based compensation <sup>3</sup>	1,393	1,407	(14)	(1%)
Net loss	(26,533)	(7,747)	(18,786)	(242%)
Diluted net loss per share	\$ (0.79)	\$ (0.23)	\$ (0.56)	(243%)

#### Select Cash Flow Data(1)(2)

	Three Mont	Three Months Ended	
(\$ in thousands)	March 31 2014	March 31 2013	
Net cash provided by (used in)			
Operating activities	\$(23,904)	\$ (9,125)	
Investing activities	389	30,477	
Financing activities	2,011	(193)	

#### Select Balance Sheet Data(1)

	March 31	December 31	March 31
(\$ in thousands)	2014	2013	2013
Total cash and marketable securities	\$100,402	\$ 130,350	\$110,932

- (1) Unaudited.
- (2) Prior year amounts have been restated to reflect a change in accounting method for the attribution of stock-based compensation. Refer to footnote 3 in the quarterly report on Form 10Q for the quarter ending March 31, 2014.
- (3) Non-cash stock-based compensation is allocated to both Research & development and Selling, general & administrative expenses.

#### **OPERATIONAL HIGHLIGHTS**

On January 31, 2014, Vanda announced that the FDA approved HETLIOZ<sup>TM</sup> 20mg capsules for the treatment of Non-24. HETLIOZ<sup>TM</sup> is the first medication approved by the FDA for the treatment of Non-24. Non-24 affects the majority of totally blind individuals and it is estimated that approximately 80,000 Americans have the disorder.

On April 21, 2014, Vanda launched HETLIOZ $^{\text{TM}}$  in the U.S. HETLIOZ $^{\text{Solutions}}$  was launched to support and facilitate the treatment of blind individuals in the U.S. living with Non-24. HETLIOZ $^{\text{TM}}$  provides patients with a host of resources including information about Non-24 and HETLIOZ $^{\text{TM}}$ , insurance support, overview of financial assistance programs, and pharmacy access.

During the first quarter of 2014, the Non-24 Disease Awareness campaign was expanded with radio and television advertisements broadcast nationwide. Our awareness campaign has resulted in over 7,000 responses by individuals who opted in to learn more about Non-24 and its treatment. The majority of responders are likely patients and friends and family of blind individuals. We have begun identifying Patient Directed Physician (PDP) targets and, over the last few weeks, our field force has called upon approximately 500 PDPs, which we believe will benefit patients as they seek appropriate treatment for their condition.

Vanda expects to file for European regulatory approval of HETLIOZ<sup>TM</sup> during 2014. This begins the effort to expand the availability of HETLIOZ<sup>TM</sup> to markets outside of the U.S. HETLIOZ<sup>TM</sup> was previously granted orphan drug designation by the European Commission for the treatment of Non-24.

Vanda recorded first quarter 2014 revenues of \$9.1 million including Fanapt® royalties of \$1.7 million. Fanapt® prescriptions, as reported by IMS, were approximately 40,600 for the first quarter of 2014. This represents a 6% decrease versus fourth quarter 2013 prescriptions and a 5% increase over first quarter 2013 Fanapt® prescriptions.

#### 2014 FINANCIAL GUIDANCE

- Total 2014 operating expenses are expected to be between \$110.0 and \$120.0 million. This includes intangible asset amortization expense of \$2.5 million and \$6.0 to \$8.0 million of non-cash stock based compensation. Total 2013 operating expenses were \$54.3 million.
- Full year 2014 expenses are expected to reflect lower research and development spending as compared to 2013 and an increase in commercial spending to support the commercial launch of HETLIOZ™ in the U.S.

Full HETLIOZ™ Prescribing Information can be found at: www.hetlioz.com.

#### **CONFERENCE CALL**

Vanda has scheduled a conference call for today, Thursday, May 8, 2014, at 10:00 AM ET. During the call, Vanda's management will discuss the first quarter 2014 financial results and other corporate activities. Investors can call 1-888-895-5271 (domestic) and 1-847-619-6547 (international) and use passcode 37132179. A replay of the call will be available beginning Thursday, May 8, 2014 at 12:30 PM ET and will be accessible until Thursday, May 15, 2014, at 11:59 PM ET. The replay call-in number is 1-888-843-7419 for domestic callers and 1-630-652-3042 for international callers. The access number is 37132179.

The conference call will be broadcast simultaneously on Vanda's website, <a href="www.vandapharma.com">www.vandapharma.com</a>. 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.

#### **ABOUT VANDA PHARMACEUTICALS INC.:**

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. For more on Vanda, please visit <a href="https://www.vandapharma.com">www.vandapharma.com</a>.

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this release, including, but not limited to, the guidance provided under "2014 FINANCIAL GUIDANCE" above, are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "goal," "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: Vanda's ability to successfully commercialize HETLIOZ™ for the treatment of Non-24 in the U.S., uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ™, Vanda's dependence on third-party manufacturers to manufacture HETLIOZ™ in sufficient quantities and quality, Vanda's limited sales and marketing infrastructure, the regulatory status of tasimelteon in Europe 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, 2013 and quarterly report on Form 10-Q for the quarter ended March 31, 2014, which are on file with the SEC and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, 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 gi

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

		Months Ended
(\$ in thousands, except per share amounts)	March 31 2014	March 31 2013 (1)
Revenues:		2013 (1)
Licensing agreement	\$ 7,452	\$ 6,606
Royalty revenue	1,691	1,462
Total revenues	9,143	8,068
Operating expenses:		
Research and development	7,263	8,111
Selling, general and administrative	27,893	4,153
Intangible asset amortization	565	369
Total operating expenses	35,721	12,633
Loss from operations	(26,578)	(4,565)
Other income	45	46
Loss before tax benefit	(26,533)	(4,519)
Tax benefit	_	_
Net loss	\$ (26,533)	\$ (4,519)
Net loss per share:		
Basic and diluted	<u>\$ (0.79)</u>	\$ (0.16)
Shares used in calculations of net loss per share:		
Basic and diluted	33,678,706	28,345,555

<sup>(1)</sup> Prior year amounts have been restated to reflect a change in accounting method for the attribution of stock-based compensation. Refer to footnote 3 in the quarterly report on Form 10Q for the quarter ending March 31, 2014.

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

(\$ in thousands) ASSETS	March 31, 2014	December 31, 2013 (1)
Current assets:		
Cash and cash equivalents	\$ 43,260	\$ 64,764
Marketable securities	57,142	65,586
Accounts receivable	1,691	2,031
Inventory	192	
Prepaid expenses and other current assets	3,132	2,703
Restricted cash	100	530
Total current assets	105,517	135,614
Property and equipment, net	2,208	2,198
Intangible asset, net	12,472	5,037
Restricted cash, non-current	785	500
Total assets	\$ 120,982	\$ 143,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 953	\$ 661
Accrued liabilities	13,164	5,180
Deferred rent	228	221
Deferred revenues	31,059	26,789
Total current liabilities	45,404	32,851
Deferred rent, non-current	2,831	2,888
Deferred revenues, non-current	51,764	63,486
Total liabilities	99,999	99,225
Stockholders' equity:		
Common stock	34	33
Additional paid-in capital	355,644	352,240
Accumulated other comprehensive income	8	21
Accumulated deficit	(334,703)	(308,170)
Total stockholders' equity	20,983	44,124
Total liabilities and stockholders' equity	\$ 120,982	\$ 143,349

<sup>(1)</sup> Prior year amounts have been restated to reflect a change in accounting method for the attribution of stock-based compensation. Refer to footnote 3 in the quarterly report on Form 10Q for the quarter ending March 31, 2014.

#### INVESTOR CONTACT:

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SOURCE Vanda Pharmaceuticals Inc.