# 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): August 7, 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

Not Applicable (Former Name or Former Address, if Changed Since Last Report)

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ck 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))
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 August 7, 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 June 30, 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® (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® in sufficient quantities and quality; Vanda's limited sales and marketing infrastructure; the regulatory status of HETLIOZ® 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 and Vanda's quarterly report on Form 10-Q for the quarter ended June 30, 2014 to be filed with the SEC. 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 August 7, 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: August 7, 2014



#### Vanda Pharmaceuticals Reports Second Quarter 2014 Results

**WASHINGTON** – August 7, 2014 – 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 second quarter ended June 30, 2014.

"We are encouraged by the early positive reception of HETLIOZ by patients, physicians and payors. We look forward to more patients benefiting from HETLIOZ in the coming months and years," said Mihael Polymeropoulos MD, President and CEO of Vanda Pharmaceuticals.

#### Key Highlights:

- As of August 6, 2014, over 420 new patient prescriptions have been written for HETLIOZ® (tasimelteon) in the U.S.
- In June 2014, Vanda announced that the European Medicines Agency (EMA) accepted for evaluation the Marketing Authorization Application for oral HETLIOZ® capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).
- In July 2014, the U.S. Patent and Trademark Office (USPTO) issued a new method of use patent for HETLIOZ® in the treatment of Non-24.

#### **SECOND QUARTER 2014 REPORTED RESULTS**

Total revenues for the second quarter of 2014 were \$10.9 million, compared to \$9.1 million for the first quarter of 2014 and \$8.3 million for the second quarter of 2013. Net product revenues related to U.S. sales of HETLIOZ® in the second quarter of 2014 were \$1.6 million.

Total operating expenses for the second quarter of 2014 were \$32.5 million, compared to \$35.7 million for the first quarter of 2014 and \$11.7 million for the second quarter of 2013. Vanda recorded a net loss of \$21.6 million for the second quarter of 2014, compared to a net loss of \$26.5 million for the first quarter of 2014 and \$3.4 million for the second quarter of 2013.

Cash, cash equivalents and marketable securities (Cash) were \$63.6 million as of June 30, 2014.

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#### Year to Date June 30, 2014 Key Financial Figures(1) (2)

	Six Month			
(\$ in thousands, except per share amounts)	June 30, 2014	June 30, 2013	Change (\$)	Change (%)
Total revenues	\$ 20,005	\$16,387	\$ 3,618	22%
Research & development expenses	10,777	14,211	(3,434)	(24%)
Selling, general & administrative expenses	56,032	9,413	46,619	495%
Non-cash stock-based compensation (3)	2,836	2,432	404	17%
Net loss	(48,108)	(7,902)	(40,206)	(509%)
Diluted net loss per share	\$ (1.42)	\$ (0.28)	\$ (1.14)	(407%)

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

	Three Mor			
(\$ in thousands, except per share amounts)	June 30, 2014	March 31, 2014	Change (\$)	Change (%)
Total revenues	\$ 10,862	\$ 9,143	\$ 1,719	19%
Research & development expenses	3,514	7,263	(3,749)	(52%)
Selling, general & administrative expenses	28,139	27,893	246	1%
Non-cash stock-based compensation (3)	1,443	1,393	50	4%
Net loss	(21,575)	(26,533)	4,958	19%
Diluted net loss per share	\$ (0.64)	\$ (0.79)	\$ 0.15	19%

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

	Six Month	Six Months Ended		
(\$ in thousands)	June 30, 2014	June 30, 2013		
Net cash provided by (used in)				
Operating activities	\$(60,569)	\$(17,168)		
Investing activities	10,756	31,428		
Financing activities	2,043	601		

#### **Select Balance Sheet Data(1)**

(\$ in thousands)	June 30, 2014	December 31 2013	June 30, 2013
Total Cash(4)	\$63,585	\$ 130,350	\$103,633

- (1) Unaudited.
- 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 June 30, 2014.
- (3) Non-cash stock-based compensation is allocated to both Research & development and Selling, general & administrative expenses.
- (4) Total Cash reflects cash, cash equivalents and marketable securities

#### **OPERATIONAL HIGHLIGHTS**

As of August 6, 2014, over 420 new patient prescriptions have been written for HETLIOZ® in the U.S. This represents growth of approximately 90% in new prescriptions since the Company's June 4, 2014 commercial update. HETLIOZ® was launched in the U.S. in April 2014 for the treatment of Non-24, a disorder which affects the majority of totally blind individuals. It is estimated that approximately 80,000 Americans have the disorder.

On July 22, 2014, a new method of use patent was issued by the USPTO for HETLIOZ® in the treatment of Non-24 (patent number 8,785,492). The '492 patent is expected to expire in 2033, potentially further extending the exclusivity protection of HETLIOZ®. In the U.S., HETLIOZ® is also covered by a composition of matter patent (patent number 5,856,529), which including a Hatch-Waxman 5-year extension is currently expected to expire in 2022. Both patents, '529 and '492, are now listed in the FDA's Orange Book.

In June 2014, the EMA accepted for evaluation Vanda's Marketing Authorization Application for oral HETLIOZ® capsules for the treatment of Non-24. HETLIOZ® was previously granted orphan drug designation by the European Commission for the treatment of Non-24.

Vanda has initiated development activities for the use of HETLIOZ® in the pediatric population with Non-24, as well as in patients with Smith-Magenis syndrome.

The VLY-686, NK1 antagonist, Phase 2 study in chronic pruritus is ongoing and results are expected in mid-2015.

#### **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 \$2.3 million and \$6.0 to \$8.0 million of non-cash stock based compensation.

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

#### **CONFERENCE CALL**

Vanda has scheduled a conference call for today, Thursday, August 7, 2014, at 10:00 AM ET. During the call, Vanda's management will discuss the second quarter 2014 financial results and other corporate activities. Investors can call 1-800-708-4540 (domestic) and 1-847-619-6397 (international) and use passcode 37729521. A replay of the call will be available beginning Thursday, August 7, 2014 at 12:30 PM ET and will be accessible until Thursday, August 14, 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 37729521.

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>.

#### 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 HETLIOZ® 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 which is on file with the SEC and available on the SEC's website at www.sec.gov and Vanda's quarterly report on Form 10-Q for the quarter ended June 30, 2014 to be filed with the SEC. 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. Therefo

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			Six Months Ended				
(\$ in thousands, except per share amounts)		June 30, 2014		June 30, 2013 (1)		June 30, 2014		June 30, 2013 (1)	
Revenues:									
HETLIOZ® product revenue (2)	\$	1,559	\$	_	\$	1,559	\$	_	
Fanapt® royalty revenue		1,539		1,641		3,230		3,103	
Fanapt® licensing agreement (3)		7,764		6,678		15,216		13,284	
Total revenues		10,862		8,319		20,005		16,387	
Operating expenses:									
Cost of sales		198		_		198		_	
Research and development		3,514		6,100		10,777		14,211	
Selling, general and administrative		28,139		5,260		56,032		9,413	
Intangible asset amortization		617		372		1,182		741	
Total operating expenses		32,468		11,732		68,189		24,365	
Loss from operations		(21,606)		(3,413)		(48,184)		(7,978)	
Other income		31		30		76		76	
Loss before tax benefit		(21,575)		(3,383)		(48,108)		(7,902)	
Tax benefit		_		_		_		_	
Net loss	\$	(21,575)	\$	(3,383)	\$	(48,108)	\$	(7,902)	
Net loss per share:									
Basic and diluted	\$	(0.64)	\$	(0.12)	\$	(1.42)	\$	(0.28)	
Shares used in calculations of net loss per share:									
Basic and diluted	33,	374,625	28,	377,254	33	3,777,207	28	3,361,340	

<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 June 30, 2014.

<sup>(2)</sup> HETLIOZ® product revenue is recognized upon delivery of product shipments to the specialty pharmacies.

<sup>(3)</sup> Fanapt® licensing agreement revenue reflects the amortization of the \$200 million upfront payment received from Novartis for the right to commercialize and develop Fanapt® in the U.S. and Canada.

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

June 30,

December 31,

(\$ in thousands)	2014	2013 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,994	\$ 64,764
Marketable securities	46,591	65,586
Accounts receivable	2,376	2,031
Inventory	1,093	_
Prepaid expenses and other current assets	4,166	2,703
Restricted cash		530
Total current assets	71,220	135,614
Property and equipment, net	2,312	2,198
Intangible asset, net	11,855	5,037
Restricted cash, non-current	785	500
Total assets	\$ 86,172	\$ 143,349
LIABILITIES AND STOCKHOLDERS' EQUITY	· · · · · · · · · · · · · · · · · · ·	
Current liabilities:		
Accounts payable	\$ 248	\$ 661
Accrued liabilities	6,753	5,180
Deferred rent	234	221
Deferred revenues	31,059	26,789
Total current liabilities	38,294	32,851
Deferred rent, non-current	2,853	2,888
Deferred revenues, non-current	44,000	63,486
Other liabilities	140	_
Total liabilities	85,287	99,225
Stockholders' equity:		
Common stock	34	33
Additional paid-in capital	357,119	352,240
Accumulated other comprehensive income	10	21
Accumulated deficit	(356,278)	(308,170)
Total stockholders' equity	885	44,124
Total liabilities and stockholders' equity	\$ 86,172	\$ 143,349

(1) 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 June 30, 2014.

#### INVESTORCONTACT:

Chad Rubin Vice President The Trout Group (646) 378-2947 crubin@troutgroup.com

SOURCE Vanda Pharmaceuticals Inc.