
**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): November 7, 2013

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)

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 November 7, 2013, 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 September 30, 2013. 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. 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 failure to obtain, or any delay in obtaining, regulatory approval for its products, particularly tasimelteon for the treatment of Non-24-Hour Disorder, or to comply with ongoing regulatory requirements; Vanda’s inability to successfully commercialize tasimelteon following regulatory approval, if any; Vanda’s inability to obtain the capital necessary to fund its research and development or commercial activities; Vanda’s failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; a lack of acceptance of Vanda’s products in the marketplace, or Vanda’s failure to become or remain profitable; Vanda’s loss of rights to develop and commercialize its products under its license and sublicense agreements; 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; delays in the completion of Vanda’s or its partners’ clinical trials; 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 research and development credits; the costs and effects of current or 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, 2012 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 September 30, 2013 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, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated November 7, 2013.

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: November 7, 2013



Vanda Pharmaceuticals Reports Third Quarter 2013 Results

WASHINGTON – November 7, 2013 – 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 third quarter ended September 30, 2013.

Key Highlights:

- *On July 29, 2013 Vanda announced that the U.S. Food and Drug Administration (FDA) accepted the filing of and granted priority review classification to Vanda's New Drug Application (NDA) for tasimelteon, a circadian regulator for the treatment of Non-24-Hour Disorder (Non-24) in the totally blind.*
- *The FDA has scheduled a Peripheral and Central Nervous System Drugs Advisory Committee Meeting on November 14, 2013, for the review of Vanda's NDA for tasimelteon, proposed trade name HETLIOZ™, for the treatment of Non-24.*
- *The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) for tasimelteon to be January 31, 2014.*
- *On August 7, 2013 Vanda completed the public offering of 4.68 million shares of common stock resulting in net proceeds of \$48.6 million.*
- *Vanda recorded third quarter 2013 revenue of \$8.7 million including royalties of \$2.0 million. Fanapt® prescriptions, as reported by IMS, were approximately 43,600 for the third quarter of 2013. This represents a 13% increase over third quarter 2012 prescriptions and a 5% increase over second quarter 2013 prescriptions.*

THIRD QUARTER 2013 REPORTED RESULTS

Total revenues for the third quarter of 2013 were \$8.7 million, compared to \$8.3 million for the same period in 2012. Third quarter 2013 revenues included \$2.0 million in Fanapt® royalties received from Novartis as compared to royalties of \$1.5 million for the third quarter of 2012.

Total operating expenses for the third quarter of 2013 were \$14.1 million, compared to \$13.7 million for the third quarter of 2012. Third quarter 2013 research and development expenses of \$8.0 million includes \$3.5 million in milestones associated with the FDA acceptance of the tasimelteon filing. The primary driver of the lower research and development expenses in the third quarter of 2013 as compared to \$10.2 million in the third quarter of 2012 was the completion of the tasimelteon Non-24 and Major Depressive Disorder efficacy studies. General and administrative expenses of \$5.7 million for the third quarter of 2013 were \$2.6 million higher than the third quarter of 2012 and reflect the increased commercial activity in preparation for a potential tasimelteon commercial launch in the United States.

Vanda recorded a net loss of \$5.4 million for the third quarter of 2013, compared to a net loss of \$5.3 million for the same period in 2012. Diluted net loss per share for the third quarter of 2013 was \$0.17, compared to a diluted net loss per share of \$0.19 for the third quarter of 2012.

Cash, cash equivalents and marketable securities (Cash) increased by \$38.5 million to \$142.2 million as of September 30, 2013, primarily as a result of the sale of common stock in Vanda's public offering in August 2013.

Year to Date September 30, 2013 Key Financial Figures¹

<i>(\$ in thousands, except per share amounts)</i>	Nine Months Ended		Change (\$)	Change (%)
	September 30 2013	September 30 2012		
Total revenues	\$ 25,096	\$ 24,807	\$ 289	1%
Research & development expenses	21,968	34,829	(12,861)	(37%)
General & administrative expenses	14,743	10,657	4,086	38%
Non-cash stock-based compensation ²	3,321	3,171	150	5%
Net loss	(12,632)	(21,295)	8,663	41%
Diluted net loss per share	\$ (0.43)	\$ (0.75)	\$ 0.32	43%

Third Quarter 2013 Key Financial Figures¹

<i>(\$ in thousands, except per share amounts)</i>	Three Months Ended		Change (\$)	Change (%)
	September 30 2013	June 30 2013		
Total revenues	\$ 8,709	\$ 8,319	\$ 390	5%
Research & development expenses	8,026	5,982	2,044	34%
General & administrative expenses	5,711	5,074	637	13%
Non-cash stock-based compensation ²	1,539	830	709	85%
Net loss	(5,380)	(3,079)	(2,301)	(75%)
Diluted net loss per share	\$ (0.17)	\$ (0.11)	\$ (0.06)	(55%)

Select Cash Flow Data¹

<i>(\$ in thousands)</i>	Nine Months Ended	
	September 30 2013	September 30 2012
Net cash provided by (used in)		
Operating activities	\$ (27,439)	\$ (31,068)
Investing activities	31,421	47,660
Financing activities	49,418	—

Select Balance Sheet Data¹

<i>(\$ in thousands)</i>	<u>September 30 2013</u>	<u>June 30 2013</u>	<u>September 30 2012</u>
Total cash and marketable securities	\$ 142,172	\$ 103,633	\$ 134,404

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

OPERATIONAL HIGHLIGHTS

On July 29, 2013, Vanda announced that the FDA accepted the filing of and granted a priority review classification to Vanda's NDA for tasimelteon, a circadian regulator for the treatment of Non-24 in the totally blind. Currently, there is no approved treatment for Non-24 and tasimelteon has the potential to address this unmet medical need. The FDA has scheduled a Peripheral and Central Nervous System Drugs Advisory Committee Meeting on November 14, 2013, for the review of Vanda's NDA for tasimelteon, proposed trade name HETLIOZ™, for the treatment of Non-24. The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) for tasimelteon to be January 31, 2014.

Vanda recorded third quarter 2013 revenue of \$8.7 million including \$6.7 million in licensing revenue related to the amortization of the upfront payment received from Novartis for U.S. and Canadian commercial rights to Fanapt® and Fanapt® royalties of \$2.0 million. Fanapt® prescriptions, as reported by IMS, were approximately 43,600 for the third quarter of 2013. This represents a 13% increase over third quarter 2012 prescriptions and a 5% increase versus second quarter 2013 prescriptions.

2013 FINANCIAL GUIDANCE

2013 expenses are expected to reflect lower research and development spending as compared to 2012 and an increase in commercial spending. Reflecting the recent public offering and year to date expenditures, Vanda now expects that it will end the year with between \$130.0 and \$135.0 million in Cash. Total 2013 operating expenses are expected to be between \$50.0 and \$55.0 million and decrease in Cash, excluding the impact of the recent public offering, is expected to be between \$35.0 and \$40.0 million.

CONFERENCE CALL

Vanda has scheduled a conference call for today, Thursday, November 7, 2013, at 10:00 AM ET. During the call, Vanda's management will discuss the third quarter 2013 financial results and other corporate activities. Investors can call 1-888-895-5271 (domestic) and 1-847-619-6547 (international) and use passcode 35919679. A replay of the call will be available beginning Thursday, November 7, 2013 at 12:00 PM ET and will be accessible until Thursday, November 14, 2013, at 5:00 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 35919679.

The conference call will be broadcast simultaneously on Vanda's website, 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.

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 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,” “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 failure to obtain, or any delay in obtaining, regulatory approval for tasimelteon for the treatment of Non-24-Hour Disorder or to comply with ongoing regulatory requirements; the costs and effects of current or potential litigation 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, 2012 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 September 30, 2013 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, 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.

####

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

	Three Months Ended		Nine Months Ended	
	September 30 2013	September 30 2012	September 30 2013	September 30 2012
<i>(\$ in thousands, except per share amounts)</i>				
Revenues:				
Licensing agreement	\$ 6,753	\$ 6,753	\$ 20,037	\$ 20,037
Royalty revenue	1,956	1,535	5,059	4,770
Total revenues	<u>8,709</u>	<u>8,288</u>	<u>25,096</u>	<u>24,807</u>
Operating expenses:				
Research and development	8,026	10,159	21,968	34,829
General and administrative	5,711	3,147	14,743	10,657
Intangible asset amortization	377	377	1,118	1,118
Total operating expenses	<u>14,114</u>	<u>13,683</u>	<u>37,829</u>	<u>46,604</u>
Loss from operations	(5,405)	(5,395)	(12,733)	(21,797)
Other income	25	69	101	502
Loss before tax benefit	(5,380)	(5,326)	(12,632)	(21,295)
Tax benefit	—	—	—	—
Net loss	<u>\$ (5,380)</u>	<u>\$ (5,326)</u>	<u>\$ (12,632)</u>	<u>\$ (21,295)</u>
Net loss per share:				
Basic	<u>\$ (0.17)</u>	<u>\$ (0.19)</u>	<u>\$ (0.43)</u>	<u>\$ (0.75)</u>
Diluted	<u>\$ (0.17)</u>	<u>\$ (0.19)</u>	<u>\$ (0.43)</u>	<u>\$ (0.75)</u>
Shares used in calculations of net loss per share:				
Basic	<u>31,332,993</u>	<u>28,226,743</u>	<u>29,363,162</u>	<u>28,226,743</u>
Diluted	<u>31,332,993</u>	<u>28,226,743</u>	<u>29,363,162</u>	<u>28,226,743</u>

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(\$ in thousands)

	<u>September 30, 2013</u>	<u>December 31, 2012</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 142,172	\$ 88,772
Marketable securities	—	31,631
Accounts receivable	1,956	1,168
Prepaid expenses and other current assets	2,412	3,967
Restricted cash, current	530	430
Total current assets	147,070	125,968
Property and equipment, net	2,106	2,348
Intangible asset, net	5,414	6,532
Restricted cash, non-current	500	600
Total assets	\$ 155,090	\$ 135,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 369	\$ 287
Accrued liabilities	4,532	5,187
Deferred rent, current	215	—
Deferred revenues, current	26,789	26,789
Total current liabilities	31,905	32,263
Deferred rent, non-current	2,945	3,005
Deferred revenues, non-current	70,238	90,275
Total liabilities	105,088	125,543
Stockholders' equity:		
Common stock	33	28
Additional paid-in capital	353,708	300,974
Accumulated other comprehensive income	—	10
Accumulated deficit	(303,739)	(291,107)
Total stockholders' equity	50,002	9,905
Total liabilities and stockholders' equity	\$ 155,090	\$ 135,448

INVESTOR CONTACT:

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

SOURCE Vanda Pharmaceuticals Inc.