
**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 12, 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))
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Item 2.02. Results of Operations and Financial Condition.

On February 12, 2013, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release and is holding a conference call regarding its results of operations and financial condition for the quarter and year ended December 31, 2012. 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 Vanda’s forward-looking statements include, among others: the inability to reach agreement with the FDA regarding Vanda’s regulatory approval strategy or proposed path to approval for tasimelteon for the treatment of Non-24; Vanda’s failure to obtain regulatory approval for tasimelteon for the treatment of Non-24 or to comply with ongoing regulatory requirements; 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 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, 2011 which is on file with the SEC and available on the SEC’s 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, 2012, which will be filed with the SEC in the first quarter of 2013. In addition to the risks described above and in Vanda’s annual report on Form 10-K, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated February 12, 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 Kelly

Name: James Kelly

Title: Chief Financial Officer

Dated: February 12, 2013

**Company Contact:**

Cristina Murphy
Senior Communications Manager
Vanda Pharmaceuticals Inc.
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Vanda Pharmaceuticals Reports Fourth Quarter 2012 and Full Year 2012 Results

WASHINGTON – February 12, 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 fourth quarter and full year ended December 31, 2012.

Key Highlights:

- *Vanda reported positive SET and RESET Phase III efficacy studies for tasimelteon in the treatment of patients with Non-24-Hour Disorder (Non-24). Study results demonstrate tasimelteon is a unique circadian regulator that resets the master body clock and improves clinical symptoms in patients with Non-24.*
- *The tasimelteon Non-24 program continues towards the goal of a projected mid-2013 New Drug Application (NDA) filing with the U.S. Food and Drug Administration (FDA).*
- *All tasimelteon activities have been discontinued related to the Major Depressive Disorder (MDD) indication. In January 2013, Vanda announced that the MAGELLAN Phase IIb/III clinical study did not meet its primary endpoint.*
- *Vanda has formally requested a re-examination of the negative opinion issued by the European Medicines Agency (EMA) recommending against approval of Fanaptum™ (oral iloperidone tablets) in the European Union.*
- *Vanda recorded full year 2012 revenue of \$32.7 million including Fanapt® royalties of \$5.9 million. Fanapt® prescriptions, as reported by IMS, were approximately 38,200 for the fourth quarter of 2012. This represents a 1% decrease versus third quarter 2012 prescriptions and a 13% increase over fourth quarter 2011 prescriptions.*

FULL YEAR 2012 REPORTED RESULTS

Total revenues for the full year 2012 were \$32.7 million, compared to \$31.3 million for 2011. Full year 2012 revenues included \$5.9 million in Fanapt® royalties received from Novartis, as compared to \$4.5 million for the prior year. Both 2012 and 2011 revenues include \$26.8 million recognized from the \$200.0 million upfront payment previously received from Novartis for Fanapt® U.S. and Canadian rights.

Total operating expenses for 2012 were \$61.0 million, compared to \$42.0 million for 2011. The primary driver of the higher expenses in 2012 was the ongoing support of the tasimelteon Non-24 and MDD clinical studies.

Vanda recorded a net loss of \$27.7 million for 2012, compared to net loss of \$9.8 million for 2011. Diluted net loss per share for 2012 was \$0.98, compared to a diluted net loss per share of \$0.35 for 2011.

Vanda's cash, cash equivalents and marketable securities as of December 31, 2012 totaled \$120.4 million.

FOURTH QUARTER 2012 REPORTED RESULTS

Total revenues for the fourth quarter of 2012 were \$7.9 million, compared to \$8.4 million for 2011. Fourth quarter 2012 revenues included \$1.2 million in Fanapt® royalties received from Novartis as compared to royalties of \$1.6 million for the fourth quarter of 2011.

Total operating expenses for the fourth quarter of 2012 and 2011 were each \$14.3 million.

Vanda recorded a net loss of \$6.4 million for the fourth quarter of 2012, compared to a net loss of \$5.5 million for the fourth quarter of 2011. Diluted net loss per share for the fourth quarter of 2012 was \$0.23, compared to a diluted net loss of \$0.20 per share for the fourth quarter of 2011.

Full Year December 31, 2012 Key Financial Figures¹

	Twelve Months Ended		Change (\$)	Change (%)
	December 31 2012	December 31 2011		
<i>(in thousands, except per share amounts)</i>				
Total revenues	\$ 32,727	\$ 31,270	\$ 1,457	5%
Research & development expenses	45,446	28,996	16,450	57%
General & administrative expenses	13,882	11,486	2,396	21%
Non-cash stock-based compensation ²	4,094	5,501	(1,407)	(26%)
Loss before tax benefit	(27,664)	(10,246)	(17,418)	(170%)
Tax benefit	—	(444)	444	100%
Net loss	(27,664)	(9,802)	(17,862)	(182%)
Diluted net loss per share	\$ (0.98)	\$ (0.35)	\$ (0.63)	(180%)

Fourth Quarter 2012 Key Financial Figures¹

	Three Months Ended		Change (\$)	Change (%)
	December 31 2012	September 30 2012		
<i>(in thousands, except per share amounts)</i>				
Total revenues	\$ 7,920	\$ 8,288	\$ (368)	(4%)
Research & development expenses	10,617	10,159	458	5%
General & administrative expenses	3,225	3,147	78	2%
Non-cash stock-based compensation ²	923	576	347	60%
Loss before tax benefit	(6,369)	(5,326)	(1,043)	(20%)
Tax benefit	—	—	—	
Net loss	(6,369)	(5,326)	(1,043)	(20%)
Diluted net loss per share	\$ (0.23)	\$ (0.19)	\$ (0.04)	(21%)

Select Cash Flow Data¹

	Twelve Months Ended	
	December 31 2012	December 31 2011
<i>(in thousands)</i>		
Net cash provided by (used in)		
Operating activities	\$ (44,917)	\$ (28,410)
Investing activities	45,754	73,749
Financing activities	12	25

Select Balance Sheet Data¹

	December 31 2012	September 30 2012	December 31 2011
<i>(in thousands)</i>			
Total cash and marketable securities	\$ 120,403	\$ 134,404	\$ 167,896

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

OPERATIONAL HIGHLIGHTS

In December 2012 and January 2013, Vanda announced positive results for two Phase III studies for tasimelteon in the treatment of Non-24. The SET Phase III study demonstrated that tasimelteon was able to entrain the master body clock as measured by melatonin and cortisol circadian rhythms. Tasimelteon was also shown to significantly improve clinical symptoms across a number of sleep and wake measures. These results provided robust evidence of direct and clinically meaningful benefits to patients with Non-24. The RESET Phase III study demonstrated the maintenance effect of 20mg of tasimelteon to entrain melatonin and cortisol circadian rhythms in individuals with Non-24. Patients treated with tasimelteon maintained their clinical benefits while patients receiving placebo showed significant deterioration in measures of nighttime sleep, daytime naps and timing of sleep. Non-24 is a serious, rare circadian rhythm disorder that affects a majority of totally blind individuals who lack light perception and cannot entrain (reset) their master body clock to the 24-hour day. Currently there is no approved treatment for Non-24.

Vanda plans to submit an NDA to the FDA in mid-2013. Vanda will meet with the FDA in Q1 of 2013 for a pre-NDA meeting on tasimelteon in the treatment of patients with Non-24.

Vanda has decided to discontinue all activities related to the MDD indication. In January, Vanda announced that the MAGELLAN Phase IIb/III clinical study in MDD did not meet the primary endpoint of a change from baseline in the Hamilton Depression Scale (HAMD-17) after 8 weeks of treatment as compared to placebo.

Vanda has formally appealed the EMA's negative opinion for Fanaptum™ (oral iloperidone tablets) and requested a re-examination of the decision by the EMA's Committee for Medicinal Product for Human Use (CHMP). In December 2012, the CHMP issued a negative opinion recommending against approval of Fanaptum™ for the treatment of schizophrenia in adult patients in the European Union.

Vanda recorded full year 2012 revenue of \$32.7 million including Fanapt® royalties of \$5.9 million. Fanapt® prescriptions, as reported by IMS, were approximately 38,200 for the fourth quarter of 2012. This represents a 1% decrease versus third quarter 2012 prescriptions and a 13% increase over fourth quarter 2011 prescriptions.

CONFERENCE CALL

Vanda has scheduled a conference call for today, Tuesday, February 12, 2013, at 10:00 AM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2012 results and other corporate activities. Investors can call 800-901-5248 (domestic) and 617-786-4512 (international) and use passcode 86594010. A replay of the call will be available beginning Tuesday, February 12, 2013 at 12:00 PM ET and will be accessible until Tuesday, February 19, 2013, 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 89804635.

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 14, 2013.

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 <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,” “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: the inability to reach agreement with the FDA regarding Vanda’s regulatory approval strategy or proposed path to approval for tasimelteon for the treatment of Non-24; Vanda’s failure to obtain regulatory approval for tasimelteon for the treatment of Non-24 or to comply with ongoing regulatory requirements; 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 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, 2011 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, 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 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)

(in thousands, except for share and per share amounts)	Three Months Ended		Twelve Months Ended	
	December 31 2012	December 31 2011	December 31 2012	December 31 2011
Revenues:				
Licensing agreement	\$ 6,752	\$ 6,752	\$ 26,789	\$ 26,789
Royalty revenue	1,168	1,618	5,938	4,481
Total revenues	7,920	8,370	32,727	31,270
Operating expenses:				
Cost of sales	129	—	129	—
Research and development	10,617	10,556	45,446	28,996
General and administrative	3,225	3,345	13,882	11,486
Intangible asset amortization	377	377	1,495	1,495
Total operating expenses	14,348	14,278	60,952	41,977
Loss from operations	(6,428)	(5,908)	(28,225)	(10,707)
Other income	59	99	561	461
Loss before tax benefit	(6,369)	(5,809)	(27,664)	(10,246)
Tax benefit	—	(286)	—	(444)
Net loss	\$ (6,369)	\$ (5,523)	\$ (27,664)	\$ (9,802)
Net loss per share:				
Basic	\$ (0.23)	\$ (0.20)	\$ (0.98)	\$ (0.35)
Diluted	\$ (0.23)	\$ (0.20)	\$ (0.98)	\$ (0.35)
Shares used in calculation of net loss per share:				
Basic	28,233,409	28,115,175	28,228,409	28,106,831
Diluted	28,233,409	28,115,175	28,228,409	28,106,831

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands)

	December 31, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 88,772	\$ 87,923
Marketable securities, current	31,631	60,961
Accounts receivable	1,168	1,618
Inventory	57	—
Prepaid expenses and other current assets	3,910	2,999
Restricted cash, current	430	—
Total current assets	<u>125,968</u>	<u>153,501</u>
Marketable securities, non-current	—	19,012
Property and equipment, net	2,348	964
Other assets, non-current	—	84
Intangible asset, net	6,532	8,027
Restricted cash, non-current	600	1,030
Total assets	<u>\$ 135,448</u>	<u>\$ 182,618</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 287	\$ 996
Accrued liabilities	5,187	3,381
Deferred rent, current	—	453
Deferred revenues, current	26,789	26,789
Total current liabilities	<u>32,263</u>	<u>31,619</u>
Non-current liabilities:		
Deferred rent, non-current	3,005	461
Deferred revenues, non-current	90,275	117,064
Total liabilities	<u>125,543</u>	<u>149,144</u>
Stockholders' equity:		
Common stock	28	28
Additional paid-in capital	300,974	296,868
Accumulated other comprehensive income	10	21
Accumulated deficit	(291,107)	(263,443)
Total stockholders' equity	<u>9,905</u>	<u>33,474</u>
Total liabilities and stockholders' equity	<u>\$ 135,448</u>	<u>\$ 182,618</u>

SOURCE Vanda Pharmaceuticals Inc.

COMPANY CONTACT:

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