
**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 9, 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 May 9, 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 March 31, 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 regulatory approval for its products or product candidates, particularly tasimelteon for the treatment of Non-24-Hour Disorder, or to comply with ongoing regulatory requirements; Vanda’s loss of rights to develop and commercialize its products, product candidates or partnered products under its license and sublicense agreements; Vanda’s failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; Vanda’s ability to successfully commercialize tasimelteon following regulatory approval, if any; 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 or its partners’ clinical trials; a failure of Vanda’s products, product candidates or partnered products to be demonstrably safe and effective; 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 its research and development or commercial activities; Vanda’s failure to identify or obtain rights to new products or product candidates; 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 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. 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 May 9, 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: May 9, 2013



Vanda Pharmaceuticals Reports First Quarter 2013 Results

WASHINGTON – May 9, 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 first quarter ended March 31, 2013.

Key Highlights:

- On March 25, 2013, Vanda announced that it held a successful Pre-New Drug Application meeting with the U.S. Food and Drug Administration (FDA). The FDA confirmed that the efficacy and safety data proposed by Vanda to be submitted in a tasimelteon New Drug Application (NDA) for Non-24-Hour Disorder (Non-24) is adequate to support filing. Vanda is targeting an NDA submission for tasimelteon for Non-24 in mid-2013.
- Vanda and Bristol-Myers Squibb (BMS) entered into an amendment to the tasimelteon licensing agreement. Subsequent to this amendment, BMS waived its option to re-acquire rights to develop and commercialize tasimelteon.
- Full year 2013 decrease in cash, cash equivalents and marketable securities (Cash) is expected to be between \$45.0 and \$50.0 million, compared to \$47.5 million for 2012. 2013 expenses are expected to reflect lower research and development spending as compared to 2012 and an increase in commercial spending that is commensurate to progress with the tasimelteon NDA filing.
- During the first quarter of 2013, Vanda withdrew its Marketing Authorization Application (MAA) for Fanaptum™ (oral iloperidone tablets) in the European Union.
- On April 18, 2013, Vanda announced that Paolo Baroldi, M.D., Ph.D. joined its management team as Senior Vice President, Chief Medical Officer.

FIRST QUARTER 2013 REPORTED RESULTS

Total revenues for the first quarter of 2013 and 2012 were each \$8.1 million. The total revenues for the first quarter of 2013 and 2012 each included \$1.5 million in Fanapt® royalties received from Novartis.

Total operating expenses for the first quarter of 2013 were \$12.3 million, compared to \$16.5 million for the first quarter of 2012. The primary driver of the lower expenses in the first quarter of 2013 was the completion of the tasimelteon Non-24 and Major Depressive Disorder efficacy studies.

Vanda recorded a net loss of \$4.2 million for the first quarter of 2013, compared to a net loss of \$8.0 million for the same period in 2012. Diluted net loss per share for the first quarter of 2013 was \$0.15, compared to a diluted net loss per share of \$0.28 for the first quarter of 2012.

Cash decreased by \$9.5 million in the first quarter of 2013, compared to decreases of \$10.6 million in the first quarter of 2012 and \$14.0 million in the fourth quarter of 2012. Vanda's Cash as of March 31, 2013 totaled \$110.9 million.

First Quarter 2013 Key Financial Figures¹

<i>(in thousands, except per share amounts)</i>	Three Months Ended		Change (\$)	Change (%)
	March 31 2013	December 31 2012		
Total revenues	\$ 8,068	\$ 7,920	\$ 148	2%
Research & development expenses	7,960	10,617	(2,657)	(25%)
General & administrative expenses	3,958	3,225	733	23%
Non-cash stock-based compensation ²	952	923	29	3%
Net loss	(4,173)	(6,369)	2,196	34%
Diluted net loss per share	\$ (0.15)	\$ (0.23)	\$ 0.08	35%

Select Cash Flow Data¹

<i>(in thousands)</i>	Three Months Ended	
	March 31 2013	March 31 2012
Net cash provided by (used in)		
Operating activities	\$ (9,125)	\$ (8,690)
Investing activities	30,477	28,861
Financing activities	(193)	—

Select Balance Sheet Data¹

<i>(in thousands)</i>	March 31 2013	December 31 2012	March 31 2012
Total cash and marketable securities	\$110,932	\$ 120,403	\$157,250

(1) Unaudited

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

OPERATIONAL HIGHLIGHTS

On March 25, 2013, Vanda announced that it held a pre-NDA meeting with the Division of Neurology Products of the FDA to discuss the regulatory path for filing an NDA for tasimelteon, a circadian regulator, for the treatment of Non-24. At the pre-NDA meeting, the FDA confirmed that the efficacy and safety data proposed by Vanda to be submitted in the tasimelteon NDA for Non-24 is adequate to support filing. The NDA supporting package that includes data from clinical pharmacology, pre-clinical pharmacology program, chemistry and manufacturing was also deemed adequate to support filing. Based on this successful completion of the pre-NDA meeting, Vanda is targeting an NDA submission for tasimelteon in mid-2013. Non-24 is a serious, rare circadian rhythm disorder that affects a majority of totally blind individuals. Currently there is no FDA approved treatment for Non-24.

Vanda continues to expand its activities in support of Non-24 disease awareness and education with professional, advocacy and patient groups. In June 2013, Vanda will present data from the SET and RESET studies at the 27th Annual Meeting of the Associated Professional Sleep Societies, SLEEP 2013, and the 95th Annual Endocrine Society Meeting, ENDO 2013. In addition, Vanda continues to build its registry of individuals who have the potential to be Non-24 patients. The U.S. based registry has over 1,500 individuals and was created to facilitate the recruitment of patients for the tasimelteon Non-24 clinical studies.

On April 25, 2013, Vanda and Bristol-Myers Squibb (BMS) entered into an amendment to the tasimelteon licensing agreement. Subsequent to this amendment, BMS waived its option to re-acquire rights to develop and commercialize tasimelteon in countries not covered by a third party development and commercialization agreement.

Vanda plans to initiate a proof of concept study for VLY-686 in Treatment Resistant Pruritus in Atopic Dermatitis in the second half of 2013. VLY-686 is a small molecule neurokinin-1 receptor (NK-1R) antagonist currently at the clinical stage of development. An inappropriate NK-1R activation either in nervous tissue or peripherally could result in pathological conditions such as substance dependence, anxiety, nausea/vomiting, and pruritus. An NK-1R antagonist may possess the ability to reduce this over-stimulation of the NK-1R, and as a result address the underlying pathophysiology of the symptoms in these conditions.

During the first quarter of 2013, Vanda withdrew its MAA submitted to the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) for Fanaptum™ for the treatment of adult patients with schizophrenia. This withdrawal was based on a request by the CHMP/Rapporteur/Co-rapporteur for Vanda to submit the results from an ongoing relapse prevention, randomized iloperidone-placebo withdrawal study in patients with schizophrenia. The results of this study will not be available in the timeframe allowed by the EMA's Centralised Procedure. Vanda intends to reassess its European regulatory strategy for Fanaptum™ once the results from the Relapse Prevention Study in Patients with Schizophrenia (REPRIEVE) being conducted by Novartis, become available.

Vanda recorded first quarter 2013 revenue of \$8.1 million including Fanapt® royalties of \$1.5 million. Fanapt® prescriptions, as reported by IMS, were approximately 38,900 for the first quarter of 2013. This represents a 9% increase over first quarter 2012 prescriptions and a 2% increase versus fourth quarter 2012 prescriptions.

On April 18, 2013, Vanda announced that Paolo Baroldi, M.D., Ph.D. joined its management team as Senior Vice President, Chief Medical Officer. He had assumed the role of Vanda's acting Chief Medical Officer in October 2012. Dr. Baroldi previously served as Vanda's Senior Vice President and Chief Medical Officer from July 2006 through January 2009. He has also served in senior clinical development positions at Galileo Research, Supernus Pharmaceuticals, Chiesi Farmaceutici SpA, and Novartis.

2013 FINANCIAL GUIDANCE

2013 financial guidance assumes a mid-year NDA submission for tasimelteon for Non-24 is accepted by the FDA for Standard Review. 2013 expenses are expected to reflect lower research and development spending as compared to 2012 and an increase in commercial spending that is commensurate to progress with the tasimelteon NDA filing.

- Full year 2013 decrease in Cash is expected to be between \$45.0 and \$50.0 million, compared to \$47.5 million for 2012.
- Total 2013 operating expenses are expected to be between \$57.0 and \$62.0 million. This includes Fanapt® intangible asset amortization of \$1.5 million and \$4.0 to \$6.0 million of non-cash stock based compensation. Total 2012 operating expenses were \$61.0 million.
- 2013 operating expense guidance assumes \$4.3 million in milestone payments due upon the acceptance by the FDA of a tasimelteon NDA submission and \$3.0 to \$4.0 million in NDA filing-related expenses.

CONFERENCE CALL

Vanda has scheduled a conference call for today, Thursday, May 9, 2013, at 10:00 AM ET. During the call, Vanda's management will discuss the first quarter 2013 financial results and other corporate activities. Investors can call 1-877-280-4962 (domestic) and 1-857-244-7319 (international) and use passcode 32610810. A replay of the call will be available beginning Thursday, May 9, 2013 at 12:00 PM ET and will be accessible until Thursday, May 16, 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 47460221.

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 regulatory approval for tasimelteon for the treatment of Non-24-Hour Disorder or to comply with ongoing regulatory requirements; 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. 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.

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

	Three Months Ended	
	March 31 2013	March 31 2012
<i>(in thousands, except for share and per share amounts)</i>		
Revenues:		
Licensing agreement	\$ 6,606	\$ 6,606
Royalty revenue	1,462	1,535
Total revenues	8,068	8,141
Operating expenses:		
Research and development	7,960	12,180
General and administrative	3,958	3,909
Intangible asset amortization	369	369
Total operating expenses	12,287	16,458
Loss from operations	(4,219)	(8,317)
Other income	46	355
Loss before tax benefit	(4,173)	(7,962)
Tax benefit	—	—
Net loss	\$ (4,173)	\$ (7,962)
Net loss per share:		
Basic	\$ (0.15)	\$ (0.28)
Diluted	\$ (0.15)	\$ (0.28)
Shares used in calculations of net loss per share:		
Basic	28,345,555	28,226,743
Diluted	28,345,555	28,226,743

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands)

March 31, 2013

December 31, 2012

ASSETS

Current assets:

Cash and cash equivalents	\$ 109,931	\$ 88,772
Marketable securities	1,001	31,631
Accounts receivable	1,462	1,168
Prepaid expenses and other current assets	3,288	3,967
Restricted cash, current	430	430
Total current assets	116,112	125,968

Property and equipment, net	2,264	2,348
Intangible asset, net	6,163	6,532
Restricted cash, non-current	600	600
Total assets	\$ 125,139	\$ 135,448

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 1,113	\$ 287
Accrued liabilities	3,874	5,187
Deferred rent, current	197	—
Deferred revenues, current	26,789	26,789
Total current liabilities	31,973	32,263

Deferred rent, non-current	3,016	3,005
Deferred revenues, non-current	83,669	90,275
Total liabilities	118,658	125,543

Stockholders' equity:

Common stock	28	28
Additional paid-in capital	301,733	300,974
Accumulated other comprehensive income	—	10
Accumulated deficit	(295,280)	(291,107)
Total stockholders' equity	6,481	9,905

Total liabilities and stockholders' equity	\$ 125,139	\$ 135,448
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COMPANY CONTACT:

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