
**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 6, 2015

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 6, 2015, 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, 2015. The full text of the press release which includes information regarding Vanda’s use of Non-GAAP financial measures, 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 2015. 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 ability to generate U.S. sales of Fanapt® for the treatment of schizophrenia; the timing and costs of Vanda’s establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.; Vanda’s dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality; Vanda’s limited sales and marketing infrastructure; the regulatory status of HETLIOZ® and Fanapt® in Europe; Vanda’s ability to successfully commercialize HETLIOZ® and Fanapt® outside the U.S.; Vanda’s ability to obtain the capital necessary to fund its research and development or commercial activities; the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the FDA’s approval of Fanapt®; 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 and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; use of existing cash, cash equivalents and marketable securities 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, 2014 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 6, 2015.

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.

Dated: May 6, 2015

By: /s/ James P. Kelly

Name: James P. Kelly

Title: Senior Vice President, Chief Financial
Officer, Secretary, and Treasurer

Vanda Pharmaceuticals Reports First Quarter 2015 Financial Results

- HETLIOZ® net product sales increased by 24% over the prior quarter to \$7.5 million, patients on active treatment grew by 22% over the prior quarter
- Fanapt® net product sales reach \$14.7 million in the first quarter since regaining rights
- Vanda reaffirms full year net product sales guidance of \$95 million to \$110 million

Conference call scheduled for 4:30 p.m. ET today

WASHINGTON – May 6, 2015 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the first quarter ended March 31, 2015.

“The first quarter of 2015 was a record quarter for product sales driven by HETLIOZ and Fanapt. As we are just at the beginning of accessing the 80,000 Non-24 patients in the U.S., the growth potential for HETLIOZ remains ahead. Similarly, the expanded patent exclusivity for Fanapt underscores the growth potential of this product through the coming decade and beyond. We are looking to further drive revenue growth through both geographic expansion and the disciplined life cycle management of our commercial products.” said Mihael H. Polymeropoulos M.D., Vanda’s President and CEO.

Financial Highlights

- First quarter of 2015 Total net product sales increased by 268% over the prior quarter to \$22.2 million, driven by the growth in HETLIOZ® sales and the acquisition of the Fanapt® product rights.
- Net loss for the first quarter of 2015 was \$10.2 million, or \$0.24 per share, compared with a net loss of \$26.5 million, or \$0.79 per share, for the same period in 2014.
- Cash, cash equivalents and marketable securities increased by \$4.5 million to \$134.3 million as of March 31, 2015, as compared to \$129.8 million as of December 31, 2014.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$7.5 million the first quarter of 2015, a 24% increase compared to \$6.0 million in the fourth quarter of 2014. As of March 31, 2015, patients on active HETLIOZ® treatment grew by 22%, compared to the fourth quarter of 2014.
- In April 2015, the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use adopted a positive opinion for HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24). A final decision is expected by the end of the second quarter of 2015.
- HETLIOZ® life cycle management activities continue to progress with a HETLIOZ® interventional study for the treatment of Smith-Magenis Syndrome and a HETLIOZ® pediatric pharmacokinetic study each expected to begin by the end of 2015.

Fanapt® (iloperidone)

- Fanapt® U.S. net product sales reached \$14.7 million in the first quarter since regaining rights. Vanda’s field sales force began promotion of Fanapt® in the U.S. in April 2015.
- During 2015, three additional Fanapt® patents were listed in the U.S. Food and Drug Administration’s (FDA) Orange Book. Fanapt® patents 8,586,610, 8,652,776 and 8,999,638 expire in November 2027, August 2030 and October 2030, respectively.

- Vanda expects to initiate a Phase II study in chronic pruritus in patients with atopic dermatitis in the fourth quarter of 2015, seeking to confirm the exploratory efficacy findings reported in the Phase II proof of concept study (2101).

Non-GAAP Financial Results

Vanda Non-GAAP Total revenues for the first quarter of 2015 were \$22.2 million, compared to Non-GAAP Total revenues of \$1.7 million for the first quarter of 2014.

For the first quarter of 2015, Non-GAAP net loss was \$4.1 million, or \$0.10 per share, compared with a Non-GAAP net loss of \$32.0 million, or \$0.95 per share, for the same period in 2014.

Vanda provides Non-GAAP financial information, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP figures. Refer to the sections of this press entitled “Non-GAAP Financial Information” and “Reconciliation of GAAP to Non-GAAP Financial Information”.

2015 Financial Guidance

Vanda affirms its prior 2015 financial guidance and expects to achieve the following financial objectives in 2015:

- Combined net product sales from both HETLIOZ® and Fanapt® of between \$95 million and \$110 million.
- HETLIOZ® net product sales of between \$40 million to \$45 million and Fanapt® net product sales of between \$55 million to \$65 million.
- Non-GAAP Operating expenses, excluding cost of sales, of between \$105 million and \$120 million.

Non-GAAP Operating expenses also excludes:

- Intangible asset amortization expense of \$13.0 million.
- Stock-based compensation of between \$8.5 million and \$10.5 million.

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

Full Fanapt® Prescribing Information, including Boxed Warnings and Important Safety Information can be found at: www.fanapt.com.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, May 6, 2015, at 4:30 PM ET. During the call, Vanda’s management will discuss the first quarter 2015 financial results and other corporate activities. Investors can call 1-800-708-4540 (domestic) or 1-847-619-6397 (international) and use passcode 39503340. A replay of the call will be available beginning Wednesday, May 6, 2015 at 7:00 PM ET and will be accessible until Tuesday, May 12, 2015, 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 passcode number is 39503340.

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.

Non-GAAP Financial Information

Vanda believes that the Non-GAAP financial information provided in this release can assist investors in understanding and assessing the ongoing economics of Vanda's business and reflect how it manages the business internally and sets operational goals. Vanda's "Non-GAAP Total revenues" excludes the Fanapt® licensing revenue. Vanda's "Non-GAAP Selling, general and administrative expenses" and "Non-GAAP Research and development expenses" exclude stock-based compensation. Vanda's "Non-GAAP Net income (loss)" and "Non-GAAP net income (loss) per share" excludes the Fanapt® licensing revenue, stock-based compensation, intangible asset amortization and gain on arbitration settlement.

Vanda believes that excluding the impact of these items better reflects the recurring economic characteristics of its business, as well as Vanda's use of financial resources and its long-term performance.

This press release includes a projection of 2015 Non-GAAP Operating expenses, excluding cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2015 Financial Guidance". This Non-GAAP financial measure is determined by excluding cost of goods sold, stock-based compensation and intangible asset amortization. Vanda is unable to reconcile this Non-GAAP guidance to GAAP because it is difficult to predict the future impact of these adjustments.

These Non-GAAP financial measures, as presented, may not be comparable to similarly titled measures reported by other companies since not all companies may calculate these measures in an identical manner and, therefore, they are not necessarily an accurate measure of comparison between companies.

The presentation of these Non-GAAP financial measures is not intended to be considered in isolation or as a substitute for guidance prepared in accordance with GAAP. The principal limitation of these Non-GAAP financial measures is that they exclude significant elements that are required by GAAP to be recorded in Vanda's financial statements. In addition, they are subject to inherent limitations as they reflect the exercise of judgments by management in determining these Non-GAAP financial measures. In order to compensate for these limitations, Vanda presents its Non-GAAP financial guidance in connection with its GAAP guidance. Investors are encouraged to review the reconciliation of the Non-GAAP financial measures to their most directly comparable GAAP financial measure.

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.

Forward-Looking Statements

Various statements in this release, including, but not limited to, the guidance provided in the heading of this press release and under "2015 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 Vanda’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 ability to generate U.S. sales of Fanapt® for the treatment of schizophrenia; the timing and costs of Vanda’s establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.; Vanda’s dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality; Vanda’s limited sales and marketing infrastructure; the regulatory status of HETLIOZ® and Fanapt® in Europe; Vanda’s ability to successfully commercialize HETLIOZ® and Fanapt® outside the U.S.; Vanda’s ability to obtain the capital necessary to fund its research and development or commercial activities; the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the FDA’s approval of Fanapt®; 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 and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; use of existing cash, cash equivalents and marketable securities 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, 2014 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.

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VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 31 2015	March 31 2014
<i>(\$ in thousands, except per share amounts)</i>		
Revenues:		
HETLIOZ® product sales, net	\$ 7,460	\$ —
Fanapt® product sales, net	14,690	—
Fanapt® royalty revenue	—	1,691
Fanapt® licensing revenue	—	7,452
Total revenues	22,150	9,143
Operating expenses:		
Cost of goods sold	5,015	—
Research and development	4,478	7,263
Selling, general and administrative	18,806	27,893
Intangible asset amortization ⁽¹⁾	4,144	565
Total operating expenses	32,443	35,721
Income (loss) from operations	(10,293)	(26,578)
Other income	72	45
Net income (loss)	\$ (10,221)	\$ (26,533)
Net income (loss) per share:		
Basic and diluted	\$ (0.24)	\$ (0.79)
Weighted average shares outstanding:		
Basic and diluted	41,744,948	33,678,706

(1) A new intangible asset was recorded in the first quarter of 2015 related to the \$25.0 million milestone obligation to Bristol-Myers Squibb due upon cumulative global net product sales of HETLIOZ® reaching \$250.0 million. The HETLIOZ® intangible asset and related amortization is recognized when reaching that sales amount is deemed probable while the actual payment will occur once the sales are realized.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(\$ in thousands)	March 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,809	\$ 60,901
Marketable securities	101,520	68,921
Accounts receivable, net	20,120	3,654
Inventory	5,215	5,170
Prepaid expenses and other current assets	2,503	3,084
Total current assets	162,167	141,730
Property and equipment, net	3,080	2,437
Intangible assets, net	47,580	26,724
Restricted cash and other	813	813
Total assets	\$ 213,640	\$ 171,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,490	\$ 835
Accrued and other current liabilities	30,299	6,951
Total current liabilities	31,789	7,786
Milestone obligation under license agreement	25,000	—
Other non-current liabilities	4,378	3,101
Total liabilities	61,167	10,887
Stockholders' equity:		
Common stock	42	41
Additional paid-in capital	450,609	448,744
Accumulated other comprehensive income	27	16
Accumulated deficit	(298,205)	(287,984)
Total stockholders' equity	152,473	160,817
Total liabilities and stockholders' equity	\$ 213,640	\$ 171,704

Reconciliation of GAAP to Non-GAAP Financial Information
VANDA PHARMACEUTICALS INC.
Reconciliation of GAAP to Non-GAAP Financial Information

	Three Months Ended	
	March 31 2015	March 31 2014
<i>(\$ in thousands, except per share amounts)</i>		
Net income (loss)	\$ (10,221)	\$ (26,533)
Adjustments:		
Fanapt® licensing revenue	—	(7,452)
Stock-based compensation	1,945	1,393
Intangible asset amortization(1)	4,144	565
Non-GAAP Net loss	<u>\$ (4,132)</u>	<u>\$ (32,027)</u>
Non-GAAP Net loss per share:		
Basic and diluted	\$ (0.10)	\$ (0.95)
Weighted average shares outstanding:		
Basic and diluted	41,744,948	33,678,706
Total revenues	\$ 22,150	\$ 9,143
Adjustment:		
Fanapt® licensing revenue	—	(7,452)
Non-GAAP Total revenues	<u>\$ 22,150</u>	<u>\$ 1,691</u>
Operating expenses	\$ 32,443	\$ 35,721
Adjustments:		
Cost of goods sold	(5,015)	—
Stock-based compensation	(1,945)	(1,393)
Intangible asset amortization(1)	(4,144)	(565)
Non-GAAP Operating expenses excluding Cost of goods sold	<u>\$ 21,339</u>	<u>\$ 33,763</u>
Research and development	\$ 4,478	\$ 7,263
Adjustment:		
Stock-based compensation	(624)	(480)
Non-GAAP Research and development	<u>\$ 3,854</u>	<u>\$ 6,783</u>
Selling, general and administrative	\$ 18,806	\$ 27,893
Adjustment:		
Stock-based compensation	(1,321)	(913)
Non-GAAP Selling, general and administrative	<u>\$ 17,485</u>	<u>\$ 26,980</u>

COMPANY CONTACT:

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