
**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): July 27, 2016

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 July 27, 2016, 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 ended June 30, 2016. 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, Vanda’s financial guidance for 2016. 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. and Europe; 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 Fanapt® in Europe; Vanda’s ability to successfully commercialize HETLIOZ® and Fanapt® outside the U.S.; Vanda’s ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights; Vanda’s ability to obtain the capital necessary to fund its research and development or commercial activities; a loss of rights to develop and commercialize Vanda’s products under its license agreements; the ability to obtain and maintain regulatory approval of Vanda’s products, and the labeling for any approved products; the timing and success of preclinical studies and clinical trials conducted by Vanda or its development partners; a failure of Vanda’s products to be demonstrably safe and effective; the size and growth of the potential markets for Vanda’s products and the ability to serve those markets; Vanda’s expectations regarding trends with respect to its revenues, costs, expenses and liabilities; 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®; the scope, progress, expansion, and costs of developing and commercializing Vanda’s products; 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, 2015 and quarterly report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may be described in those sections of Vanda’s quarterly report on Form 10-Q for the quarter ended June 30, 2016, to be filed with the SEC in the third quarter of 2016. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated July 27, 2016.

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: July 27, 2016

By: /s/ Richard Gulino

Name: Richard Gulino

Title: Senior Vice President, General Counsel



Vanda Pharmaceuticals Reports Second Quarter 2016 Financial Results

- *HETLIOZ® net product sales grew to \$17.5 million in the second quarter 2016*
- *Fanapt® net product sales grew to \$18.6 million in the second quarter 2016*
- *Vanda reiterates 2016 net product sales guidance of \$143 million to \$153 million*

WASHINGTON – July 27, 2016 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the second quarter ended June 30, 2016.

“Vanda’s commercial business continues to demonstrate strong progress and growth,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO. “We look forward to our planned launch of HETLIOZ in Germany in the third quarter and the opportunity to bring an important therapy to Non-24 patients in Europe.”

Key Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were \$36.0 million during the second quarter of 2016, an 8% increase compared to \$33.3 million in the first quarter of 2016 and a 31% increase compared to \$27.6 million in the second quarter of 2015.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$17.5 million in the second quarter of 2016, an 8% increase compared to \$16.2 million in the first quarter of 2016 and a 74% increase compared to \$10.0 million in the second quarter of 2015.
- A HETLIOZ® product launch in Germany is planned for the third quarter of 2016.
- Enrollment in the Smith-Magenis Syndrome (SMS) open label interventional study is ongoing. An SMS placebo controlled Phase III study is expected to begin in the second half of 2016.
- The Pediatric Non-24 pharmacokinetic study of the HETLIOZ® liquid formulation is enrolling. A Phase III study is expected to begin in 2017.
- The screening of patients for a Jet Lag Disorder (JLD) Phase II proof of concept study began during the second quarter of 2016. Results from the JLD study are expected in the first half 2017.

Fanapt® (iloperidone)

- Fanapt® net product sales were \$18.6 million for the second quarter of 2016, a 9% increase compared to \$17.1 million in the first quarter of 2016 and a 6% increase compared to \$17.6 million in the second quarter of 2015.
- In May 2016, the U.S. Food and Drug Administration (FDA) approved Vanda’s supplemental New Drug Application (sNDA) for Fanapt®, modifying and expanding the prescribing information for the use of Fanapt® as a maintenance treatment for schizophrenia in adults. The FDA granted three years of marketing exclusivity for the changes related to the approval of the sNDA.
- A review of the Marketing Authorization Application for oral Fanaptum® tablets by the European Medicines Agency (EMA) for the treatment of schizophrenia in adults is ongoing. An opinion by the EMA’s Committee for Medicinal Products for Human Use (CHMP) is expected in the first quarter of 2017.

Tradipitant

- Enrollment in a tradipitant Phase II proof of concept study for the treatment of chronic pruritus in patients with atopic dermatitis is ongoing. Results are expected in the first half of 2017.
- A tradipitant Phase II proof of concept study for the treatment of gastroparesis is expected to begin enrolling patients in the fourth quarter of 2016. Results are expected in the second half of 2017.

Cash, cash equivalents and marketable securities (Cash) were \$136.0 million as of June 30, 2016, representing a decrease to Cash of \$2.3 million in the second quarter of 2016.

Non-GAAP Financial Results

For the second quarter of 2016, Non-GAAP net income was \$0.4 million, compared to a Non-GAAP net loss of \$0.4 million, for the second quarter of 2015.

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 release entitled “Non-GAAP Financial Information” and “Reconciliation of GAAP to Non-GAAP Financial Information.”

2016 Financial Guidance

Vanda reiterates its prior 2016 financial guidance with an update to stock-based compensation guidance and expects to achieve the following financial objectives in 2016:

- Combined net product sales from both HETLIOZ® and Fanapt® of between \$143 and \$153 million.
- HETLIOZ® net product sales of between \$73 and \$78 million and Fanapt® net product sales of between \$70 and \$75 million.
- Non-GAAP Operating expenses, excluding Cost of goods sold, of between \$125 and \$135 million.
- Non-GAAP Operating expenses excludes intangible asset amortization expense of \$10.9 million and stock-based compensation of between \$8 and \$10 million. Prior guidance for stock-based compensation was between \$9 and \$11 million.
- Year end 2016 Cash is expected to be between \$123 and \$143 million.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, July 27, 2016, at 4:30 PM ET. During the call, Vanda’s management will discuss the second quarter 2016 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 42972056. A replay of the call will be available on Wednesday, July 27, 2016, beginning at 7:00 PM ET and will be accessible until Wednesday, August 3, 2016, 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 42972056.

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 press 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 Selling, general and administrative expenses" and "Non-GAAP Research and development expenses" exclude stock-based compensation. Vanda's "Non-GAAP Net income (loss)," "Non-GAAP Net income (loss) per share" and "Non-GAAP Operating expenses excluding Cost of goods sold" exclude stock-based compensation and intangible asset amortization.

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 2016 Non-GAAP Operating expenses, excluding Cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2016 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 our Non-GAAP financial measures to their most directly comparable GAAP financial measure.

About Vanda Pharmaceuticals Inc.

Vanda is a specialty pharmaceutical company focused on the development and commercialization of novel therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release, including, but not limited to, the guidance provided in the subheading to this release and under “2016 Financial Guidance” above, are “forward-looking statements” under the securities laws. 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 assumptions regarding its ability to continue to grow its business in the U.S., Vanda’s ability to successfully commercialize 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, 2015, which is on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may be described in those sections of Vanda’s quarterly report on Form 10-Q for the quarter ended June 30, 2016, to be filed with the SEC in the third quarter of 2016. 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		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
<i>(\$ in thousands, except per share amounts)</i>				
Revenues:				
HETLIOZ® product sales, net	\$ 17,460	\$ 10,017	\$ 33,661	\$ 17,477
Fanapt® product sales, net	18,569	17,565	35,630	32,255
Total revenues	36,029	27,582	69,291	49,732
Operating expenses:				
Cost of goods sold	6,494	5,766	12,450	10,781
Research and development	6,700	5,946	14,248	10,424
Selling, general and administrative	24,682	18,386	53,972	37,192
Intangible asset amortization	2,942	2,942	5,885	7,086
Total operating expenses	40,818	33,040	86,555	65,483
Loss from operations	(4,789)	(5,458)	(17,264)	(15,751)
Other income	171	72	288	144
Net loss	\$ (4,618)	\$ (5,386)	\$ (16,976)	\$ (15,607)
Net loss per share, basic and diluted	\$ (0.11)	\$ (0.13)	\$ (0.39)	\$ (0.37)
Weighted average shares outstanding, basic and diluted	43,202,751	41,991,578	43,153,598	41,868,944

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(\$ in thousands)	June 30 2016	December 31 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,194	\$ 50,843
Marketable securities	112,795	92,337
Accounts receivable, net	14,030	16,331
Inventory	927	1,294
Prepaid expenses and other current assets	9,430	5,742
Total current assets	160,376	166,547
Property and equipment, net	4,246	4,570
Intangible assets, net	32,867	38,752
Non-current inventory and other	4,549	3,181
Total assets	\$ 202,038	\$ 213,050
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 17,933	\$ 15,767
Accrued government and other rebates	33,828	35,550
Total current liabilities	51,761	51,317
Milestone obligation under license agreement	25,000	25,000
Other non-current liabilities	3,663	3,706
Total liabilities	80,424	80,023
Stockholders' equity:		
Common stock	43	43
Additional paid-in capital	466,272	460,794
Accumulated other comprehensive income	124	39
Accumulated deficit	(344,825)	(327,849)
Total stockholders' equity	121,614	133,027
Total liabilities and stockholders' equity	\$ 202,038	\$ 213,050

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

<i>(in thousands, except for share and per share amounts)</i>	Three Months Ended		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Net loss	\$ (4,618)	\$ (5,386)	\$ (16,976)	\$ (15,607)
Adjustments:				
Stock-based compensation	2,074	2,068	4,340	4,013
Intangible asset amortization	2,942	2,942	5,885	7,086
Non-GAAP Net income (loss)	<u>\$ 398</u>	<u>\$ (376)</u>	<u>\$ (6,751)</u>	<u>\$ (4,508)</u>
Non-GAAP Net income (loss) per share, basic	\$ 0.01	\$ (0.01)	\$ (0.16)	\$ (0.11)
Weighted average shares outstanding, basic	43,202,751	41,991,578	43,153,598	41,868,944
Operating expenses	\$ 40,818	\$ 33,040	\$ 86,555	\$ 65,483
Adjustments:				
Cost of goods sold	(6,494)	(5,766)	(12,450)	(10,781)
Stock-based compensation	(2,074)	(2,068)	(4,340)	(4,013)
Intangible asset amortization	(2,942)	(2,942)	(5,885)	(7,086)
Non-GAAP Operating expenses excluding Cost of goods sold	<u>\$ 29,308</u>	<u>\$ 22,264</u>	<u>\$ 63,880</u>	<u>\$ 43,603</u>
Research and development	\$ 6,700	\$ 5,946	\$ 14,248	\$ 10,424
Adjustment:				
Stock-based compensation	(489)	(603)	(1,013)	(1,227)
Non-GAAP Research and development	<u>\$ 6,211</u>	<u>\$ 5,343</u>	<u>\$ 13,235</u>	<u>\$ 9,197</u>
Selling, general and administrative	\$ 24,682	\$ 18,386	\$ 53,972	\$ 37,192
Adjustment:				
Stock-based compensation	(1,585)	(1,465)	(3,327)	(2,786)
Non-GAAP Selling, general and administrative	<u>\$ 23,097</u>	<u>\$ 16,921</u>	<u>\$ 50,645</u>	<u>\$ 34,406</u>

COMPANY CONTACT:

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