
**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 2, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 2, 2017, 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 March 31, 2017. 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 2017. 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 assumptions regarding its ability to continue to grow its business in the U.S., Vanda’s ability to successfully commercialize HETLIOZ® in Europe and obtain European Marketing Authorization for oral Fanaptum®, Vanda’s ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights, 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, 2016, 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 March 31, 2017, to be filed with the SEC in the second quarter of 2017. 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 2, 2017.

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 2, 2017

By: /s/ Richard L. Gulino

Name: Richard L. Gulino

Title: Senior Vice President, General Counsel



Vanda Pharmaceuticals Reports First Quarter 2017 Financial Results

- Total net product sales were \$37.4 million in the first quarter of 2017
- Vanda reiterates 2017 net product sales guidance of \$165 million to \$175 million

WASHINGTON – May 2, 2017 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the first quarter ended March 31, 2017.

“We are pleased with the progress made in the first quarter of 2017 with the continued growth of our HETLIOZ business and the successful expansion of the Fanapt U.S. field sales team,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO. “Our research and development pipeline is advancing and the tradipitant program is nearing completion of the enrollment stage of the pruritus randomized clinical study. We look forward to sharing the pruritus study results in the third quarter of 2017.”

Key Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were \$37.4 million during the first quarter of 2017, a 2% decrease compared to \$38.2 million in the fourth quarter of 2016 and a 12% increase compared to \$33.3 million the first quarter of 2016.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$20.2 million in the first quarter of 2017, a 5% increase compared to \$19.3 million in the fourth quarter of 2016 and a 25% increase compared to \$16.2 million in the first quarter of 2016.

Fanapt® (iloperidone)

- Fanapt® net product sales were \$17.2 million in the first quarter of 2017, a 9% decrease compared to \$18.9 million in the fourth quarter of 2016 and a 1% increase compared to \$17.1 million in the first quarter of 2016.
- An expansion of the Fanapt® U.S. field sales team was completed during the first quarter of 2017.

Research and Development

HETLIOZ®

- Enrollment of patients for a Jet Lag Disorder clinical study is ongoing. Results are expected in the second half of 2017.
- Enrollment in the Smith-Magenis Syndrome clinical study is ongoing with results expected in 2018.
- A pharmacokinetic study of the HETLIOZ® pediatric formulation is enrolling with results expected in 2018.

Fanapt®

- The Marketing Authorization Application (MAA) for oral Fanaptum® tablets is under evaluation by the European Medicines Agency for the treatment of schizophrenia in adults. A decision on the Fanaptum® MAA is expected during the second half of 2017.

Tradipitant

- Enrollment in a tradipitant clinical study for the treatment of chronic pruritus in patients with atopic dermatitis is almost complete. Results are expected in the third quarter of 2017.

- A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected in the fourth quarter of 2017.

- On March 29, 2017, Vanda announced that it had entered into a license agreement with the University of California San Francisco (UCSF) to develop and commercialize a portfolio of CFTR activators and inhibitors.
- Vanda intends to complete the technology transfer activities from UCSF and initiate investigational new drug enabling studies for several CFTR indications during 2017.

Cash, cash equivalents and marketable securities (Cash) were \$137.8 million as of March 31, 2017, representing a decrease to Cash of \$3.6 million during the first quarter of 2017.

Non-GAAP Financial Results

For the first quarter of 2017, Non-GAAP net loss was \$4.9 million, or \$0.11 per share, compared to a Non-GAAP net loss of \$7.1 million, or \$0.17 per share, for the first quarter of 2016.

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.”

2017 Financial Guidance

Vanda reiterates its prior 2017 financial guidance and expects to achieve the following financial objectives in 2017:

<u>Financial Objectives</u>	<u>2017 Guidance</u>
Combined net product sales from both HETLIOZ® and Fanapt®	\$165 to \$175 million
HETLIOZ® net product sales	\$88 to \$93 million
Fanapt® net product sales	\$77 to \$82 million
Non-GAAP Operating expenses, excluding Cost of goods sold(1)	\$162 to \$172 million
Intangible asset amortization	\$1.7 million
Stock-based compensation	\$9 to \$12 million
Year-end 2017 Cash	\$121 to \$141 million

(1) *Non-GAAP Operating expenses, excludes cost of goods sold, intangible asset amortization and stock-based compensation.*

Conference Call

Vanda has scheduled a conference call for today, Tuesday, May 2, 2017, at 4:30 PM ET. During the call, Vanda’s management will discuss the first quarter 2017 financial results and other corporate activities. Investors can call 1-800-708-4539 (domestic) or 1-847-619-6396 (international) and use passcode 44748467. A replay of the call will be available on Tuesday, May 2, 2017, beginning at 7:00 PM ET and will be accessible until Tuesday, May 9, 2017, 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 44748467.

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 2017 Non-GAAP Operating expenses, excluding Cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2017 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 global biopharmaceutical company focused on the development and commercialization of innovative 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 “2017 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 obtain European Marketing Authorization for oral Fanaptum® 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, 2016, 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 fiscal quarter ended March 31, 2017, to be filed with the SEC in the second quarter of 2017. 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
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended	
	March 31 2017	March 31 2016
Revenues:		
HETLIOZ® product sales, net	\$ 20,182	\$ 16,201
Fanapt® product sales, net	17,233	17,061
Total revenues	<u>37,415</u>	<u>33,262</u>
Operating expenses:		
Cost of goods sold excluding amortization	4,003	5,956
Research and development	10,567	7,548
Selling, general and administrative	30,297	29,290
Intangible asset amortization	454	2,943
Total operating expenses	<u>45,321</u>	<u>45,737</u>
Loss from operations	(7,906)	(12,475)
Other income	280	117
Loss before income taxes	(7,626)	(12,358)
Provision for income taxes	19	—
Net loss	<u>\$ (7,645)</u>	<u>\$ (12,358)</u>
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.29)
Weighted average shares outstanding, basic and diluted	44,398,359	43,104,462

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31	December 31
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,111	\$ 40,426
Marketable securities	117,645	100,914
Accounts receivable, net	17,751	20,268
Inventory	816	779
Prepaid expenses and other current assets	12,239	11,788
Total current assets	168,562	174,175
Property and equipment, net	5,461	5,015
Intangible assets, net	27,365	27,819
Non-current inventory and other	3,332	3,365
Total assets	\$ 204,720	\$ 210,374
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 18,025	\$ 16,196
Accrued government and other rebates	29,943	34,124
Milestone obligation under license agreement	25,000	—
Total current liabilities	72,968	50,320
Milestone obligation under license agreement	—	25,000
Other non-current liabilities	3,610	3,724
Total liabilities	76,578	79,044
Stockholders' equity:		
Common stock	45	44
Additional paid-in capital	481,551	477,087
Accumulated other comprehensive income	50	58
Accumulated deficit	(353,504)	(345,859)
Total stockholders' equity	128,142	131,330
Total liabilities and stockholders' equity	\$ 204,720	\$ 210,374

VANDA PHARMACEUTICALS INC.
Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended	
	March 31 2017	March 31 2016
Net loss	\$ (7,645)	\$ (12,358)
Adjustments:		
Stock-based compensation	2,256	2,266
Intangible asset amortization	454	2,943
Non-GAAP Net loss	<u>\$ (4,935)</u>	<u>\$ (7,149)</u>
Non-GAAP Net loss per share, basic	\$ (0.11)	\$ (0.17)
Weighted average shares outstanding, basic	44,398,359	43,104,462
Operating expenses	\$ 45,321	\$ 45,737
Adjustments:		
Cost of goods sold excluding amortization	(4,003)	(5,956)
Stock-based compensation	(2,256)	(2,266)
Intangible asset amortization	(454)	(2,943)
Non-GAAP Operating expenses excluding		
Cost of goods sold	<u>\$ 38,608</u>	<u>\$ 34,572</u>
Research and development	\$ 10,567	\$ 7,548
Adjustment:		
Stock-based compensation	(409)	(524)
Non-GAAP Research and development	<u>\$ 10,158</u>	<u>\$ 7,024</u>
Selling, general and administrative	\$ 30,297	\$ 29,290
Adjustment:		
Stock-based compensation	(1,847)	(1,742)
Non-GAAP Selling, general and administrative	<u>\$ 28,450</u>	<u>\$ 27,548</u>

COMPANY CONTACT:

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