
**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 15, 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))
-
-

Item 2.02. Results of Operations and Financial Condition.

On February 15, 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 and year ended December 31, 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 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 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 September 30, 2016, which are on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may be set forth in those sections of Vanda’s annual report on Form 10-K for the year ended December 31, 2016, to be filed with the SEC in the first 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated February 15, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 15, 2017

VANDA PHARMACEUTICALS INC.

By: /s/ Richard L. Gulino

Name: Richard L. Gulino

Title: Senior Vice President, General Counsel



Vanda Pharmaceuticals Reports Fourth Quarter 2016 and Full Year 2016 Financial Results

- Full year 2016 total revenues grew to \$146 million, a 33% increase compared to 2015

WASHINGTON – February 15, 2017 – Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: [VNDA](#)), today announced financial and operational results for the fourth quarter and full year ended December 31, 2016.

“2016 was an exceptional year for Vanda as we continued to demonstrate strong growth in our commercial business and secured long-term exclusivity for Fanapt,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO. “In addition, our emerging pipeline with important 2017 milestones underscores Vanda’s commitment to bringing important new treatment options to patients and the creation of shareholder value.”

Key Highlights:

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$19.3 million in the fourth quarter of 2016, a 3% increase compared to \$18.7 million in the third quarter of 2016 and a 27% increase compared to \$15.1 million in the fourth quarter of 2015.
- HETLIOZ® net product sales were \$71.7 million for the full year 2016, a 62% increase compared to \$44.3 million for the full year 2015.

Fanapt® (iloperidone)

- Fanapt® net product sales were \$18.9 million for the fourth quarter of 2016, a 4% decrease compared to \$19.8 million in the third quarter of 2016 and a 13% increase compared to \$16.7 million in the fourth quarter of 2015.
- Fanapt® net product sales were \$74.3 million for the full year 2016, a 13% increase compared to \$65.6 million for the full year 2015.
- An expansion of the Fanapt® U.S. field sales team is expected to be completed during the first quarter of 2017.

Cash, cash equivalents and marketable securities (Cash) were \$141.3 million as of December 31, 2016, representing a decrease to Cash of \$1.8 million during 2016.

Research and Development Progress and Objectives

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 (SMS) 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.
- An assessment of new Fanapt® clinical opportunities is ongoing.

Tradipitant

- Enrollment in a tradipitant clinical study for the treatment of chronic pruritus in patients with atopic dermatitis is approaching completion. Results are expected in mid 2017.
- A tradipitant clinical study for the treatment of gastroparesis began enrolling patients in the fourth quarter of 2016. Results are expected in the fourth quarter of 2017.

Trichostatin A

- Vanda expects to submit an investigational new drug application to the FDA in mid 2017 for trichostatin A, which will seek clearance to begin a clinical study of hematologic malignancies.

Non-GAAP Financial Results

For the fourth quarter of 2016, Non-GAAP net income was \$3.6 million, compared to a Non-GAAP net loss of \$10.0 million for the fourth quarter of 2015. Vanda Non-GAAP net income was \$1.5 million for the full year 2016, compared to a Non-GAAP net loss of \$18.9 million for the full year 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 entitled “Non-GAAP Financial Information” and “Reconciliation of GAAP to Non-GAAP Financial Information.”

2017 Financial Guidance

Vanda expects to achieve the following financial objectives in 2017:

Financial Objectives	2017 Guidance
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, Wednesday, February 15, 2017, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2016 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 44159815. A replay of the call will be available on Wednesday, February 15, 2017, beginning at 7:00 PM ET and will be accessible until Wednesday, February 22, 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 44159815.

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 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 September 30, 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 annual report on Form 10-K for the fiscal year ended December 31, 2016, to be filed with the SEC in the first 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.

####

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended		Year Ended	
	December 31 2016	December 31 2015	December 31 2016	December 31 2015
Revenues:				
HETLIOZ® product sales, net	\$ 19,295	\$ 15,143	\$ 71,671	\$ 44,302
Fanapt® product sales, net	18,949	16,706	74,346	65,623
Total revenues	<u>38,244</u>	<u>31,849</u>	<u>146,017</u>	<u>109,925</u>
Operating expenses:				
Cost of goods sold	5,272	6,171	24,712	23,462
Research and development	7,614	8,747	29,156	29,145
Selling, general and administrative	23,907	28,881	99,787	84,531
Intangible asset amortization	2,105	2,943	10,933	12,972
Total operating expenses	<u>38,898</u>	<u>46,742</u>	<u>164,588</u>	<u>150,110</u>
Loss from operations	(654)	(14,893)	(18,571)	(40,185)
Other income	154	95	665	320
Loss before income taxes	(500)	(14,798)	(17,906)	(39,865)
Provision for income taxes	104	—	104	—
Net loss	<u>\$ (604)</u>	<u>\$ (14,798)</u>	<u>\$ (18,010)</u>	<u>\$ (39,865)</u>
Net loss per share:				
Basic	\$ (0.01)	\$ (0.35)	\$ (0.41)	\$ (0.94)
Diluted	\$ (0.01)	\$ (0.35)	\$ (0.41)	\$ (0.94)
Weighted average shares outstanding:				
Basic	43,968,730	42,815,291	43,449,441	42,250,254
Diluted	43,968,730	42,815,291	43,449,441	42,250,254

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

	December 31	December 31
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 40,426	\$ 50,843
Marketable securities	100,914	92,337
Accounts receivable, net	20,268	16,331
Inventory	779	1,294
Prepaid expenses and other current assets	11,788	5,742
Total current assets	174,175	166,547
Property and equipment, net	5,015	4,570
Intangible assets, net	27,819	38,752
Non-current inventory and other	3,365	3,181
Total assets	<u>\$ 210,374</u>	<u>\$ 213,050</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 16,196	\$ 15,767
Accrued government and other rebates	34,124	35,550
Total current liabilities	50,320	51,317
Milestone obligation under license agreement	25,000	25,000
Other non-current liabilities	3,724	3,706
Total liabilities	79,044	80,023
Stockholders' equity:		
Common stock	44	43
Additional paid-in capital	477,087	460,794
Accumulated other comprehensive income	58	39
Accumulated deficit	(345,859)	(327,849)
Total stockholders' equity	131,330	133,027
Total liabilities and stockholders' equity	<u>\$ 210,374</u>	<u>\$ 213,050</u>

VANDA PHARMACEUTICALS INC.

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

	Three Months Ended		Year Ended	
	December 31 2016	December 31 2015	December 31 2016	December 31 2015
Net loss	\$ (604)	\$ (14,798)	\$ (18,010)	\$ (39,865)
Adjustments:				
Stock-based compensation	2,103	1,887	8,543	7,961
Intangible asset amortization	2,105	2,943	10,933	12,972
Non-GAAP Net income (loss)	\$ 3,604	\$ (9,968)	\$ 1,466	\$ (18,932)
Non-GAAP Net income (loss) per share, basic	\$ 0.08	\$ (0.23)	\$ 0.03	\$ (0.45)
Weighted average shares outstanding, basic	43,968,730	42,815,291	43,449,441	42,250,254
Operating expenses	\$ 38,898	\$ 46,742	\$ 164,588	\$ 150,110
Adjustments:				
Cost of goods sold	(5,272)	(6,171)	(24,712)	(23,462)
Stock-based compensation	(2,103)	(1,887)	(8,543)	(7,961)
Intangible asset amortization	(2,105)	(2,943)	(10,933)	(12,972)
Non-GAAP Operating expenses excluding Cost of goods sold	\$ 29,418	\$ 35,741	\$ 120,400	\$ 105,715
Research and development	\$ 7,614	\$ 8,747	\$ 29,156	\$ 29,145
Adjustment:				
Stock-based compensation	(535)	(526)	(2,087)	(2,269)
Non-GAAP Research and development	\$ 7,079	\$ 8,221	\$ 27,069	\$ 26,876
Selling, general and administrative	\$ 23,907	\$ 28,881	\$ 99,787	\$ 84,531
Adjustment:				
Stock-based compensation	(1,568)	(1,361)	(6,456)	(5,692)
Non-GAAP Selling, general and administrative	\$ 22,339	\$ 27,520	\$ 93,331	\$ 78,839

COMPANY CONTACT:

Jim Kelly
Senior Vice President & Chief Financial Officer
Vanda Pharmaceuticals Inc.
(202) 734-3428
jim.kelly@vandapharma.com

SOURCE Vanda Pharmaceuticals Inc.