
**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): November 7, 2018

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 November 7, 2018, 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 September 30, 2018. 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 2018. 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 complete the clinical development and obtain regulatory approval of tradipitant for the treatment of atopic dermatitis and the treatment of gastroparesis, 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, 2017 and quarterly report on Form 10-Q for the quarter ended June 30, 2018, 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 September 30, 2018, to be filed with the SEC in the fourth quarter of 2018. 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 November 7, 2018.

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.

Dated: November 7, 2018

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel and
Secretary



Vanda Pharmaceuticals Reports Third Quarter 2018 Financial Results

- *Hetlioz® net product sales grew to \$29.9 million in the third quarter of 2018, a 34% increase compared to the third quarter of 2017*
- *Results from clinical studies of tradipitant in gastroparesis and HETLIOZ® in Smith-Magenis Syndrome are expected by the end of 2018*

WASHINGTON – November 7, 2018 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2018.

Key Highlights:

- Vanda reiterates 2018 net product sales guidance of \$180 million to \$200 million.
- Total net product sales from HETLIOZ® and Fanapt® were \$49.1 million during the third quarter of 2018, a 4% increase compared to \$47.4 million in the second quarter of 2018 and a 19% increase compared to \$41.3 million in the third quarter of 2017.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales were \$29.9 million in the third quarter of 2018, a 7% increase compared to \$28.0 million in the second quarter of 2018 and a 34% increase compared to \$22.3 million in the third quarter of 2017.

Fanapt® (iloperidone)

- Fanapt® net product sales were \$19.2 million in the third quarter of 2018, a less than 1% decrease compared to \$19.3 million in the second quarter of 2018 and a less than 1% increase compared to \$19.1 million in the third quarter of 2017.

Research and Development

Tradipitant

- Enrollment in the clinical study of tradipitant in gastroparesis is complete. Results are expected by the end of 2018.
- The Phase III study (EPIONE) of tradipitant in atopic dermatitis is ongoing.

HETLIOZ® (tasimelteon)

- Enrollment in the clinical study of HETLIOZ® in Smith-Magenis Syndrome is complete. Results are expected by the end of 2018.
- Vanda submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration for HETLIOZ® in jet lag disorder and expects a filing date by the end of 2018.
- In September, a HETLIOZ® driving study demonstrated no impairment of next day driving performance.

Fanapt® (iloperidone)

- A pharmacokinetic study of the long acting injectable (Depot) formulation of Fanapt® enrolled its first patient during October 2018.

VTR-297 (histone deacetylase (HDAC) inhibitor)

- The Phase I study (1101) of VTR-297 in patients with hematologic malignancies randomized its first patient in October 2018.

Cash, cash equivalents and marketable securities (Cash) were \$240.6 million as of September 30, 2018. During the third quarter of 2018, Cash increased by \$9.4 million.

Non-GAAP Financial Results

For the third quarter of 2018, Non-GAAP net income was \$10.4 million, compared to Non-GAAP net loss of \$1.3 million for the third quarter of 2017.

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.”

2018 Financial Guidance

Vanda reiterates its prior 2018 net product sales guidance and provides an update to Non-GAAP Operating Expenses, Intangible Asset Amortization and Year-End 2018 Cash guidance and expects to achieve the following financial objectives in 2018:

Full Year 2018 Financial Objectives	Full Year 2018 Guidance
Combined net product sales from both HETLIOZ® and Fanapt®	\$180 to \$200 million
HETLIOZ® net product sales	\$108 to \$118 million
Fanapt® net product sales	\$72 to \$82 million
Non-GAAP Operating expenses, excluding Cost of goods sold	\$140 to \$150 million as compared to prior guidance of \$153 to \$163 million
Intangible asset amortization	\$1.5 million as compared to prior guidance of \$1.7 million
Stock-based compensation	\$11 to \$15 million
Year-end 2018 Cash	\$240 to \$250 million as compared to prior guidance of \$225 to \$235 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, November 7, 2018, at 4:30 PM ET. During the call, Vanda’s management will discuss the third quarter 2018 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405

(international) and use passcode 47697858. A replay of the call will be available on Wednesday, November 7, 2018, beginning at 7:00 PM ET and will be accessible until Wednesday, November 14, 2018, 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 47697858.

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 2018 Non-GAAP Operating expenses, excluding Cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2018 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 under “2018 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 complete the clinical development and obtain regulatory approval of tradipitant for the treatment of atopic dermatitis and the treatment of gastroparesis, 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, 2017 and quarterly report on Form 10-Q for the quarter ended June 30, 2018, 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 September 30, 2018, to be filed with the SEC in the fourth quarter of 2018. 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		Nine Months Ended	
	September 30 2018	September 30 2017	September 30 2018	September 30 2017
Revenues:				
HETLIOZ® product sales, net	\$ 29,923	\$ 22,279	\$ 83,391	\$ 64,968
Fanapt® product sales, net	19,212	19,057	56,686	55,839
Total revenues	49,135	41,336	140,077	120,807
Operating expenses:				
Cost of goods sold excluding amortization	5,068	4,525	14,841	13,057
Research and development	11,390	10,178	30,672	28,393
Selling, general and administrative	26,047	31,124	80,829	92,792
Intangible asset amortization	397	432	1,147	1,318
Total operating expenses	42,902	46,259	127,489	135,560
Income (loss) from operations	6,233	(4,923)	12,588	(14,753)
Other income	1,030	396	2,440	1,073
Income (loss) before income taxes	7,263	(4,527)	15,028	(13,680)
Provision for income taxes	92	23	180	49
Net income (loss)	<u>\$ 7,171</u>	<u>\$ (4,550)</u>	<u>\$ 14,848</u>	<u>\$ (13,729)</u>
Net income (loss) per share, basic	\$ 0.14	\$ (0.10)	\$ 0.30	\$ (0.31)
Net income (loss) per share, diluted	\$ 0.13	\$ (0.10)	\$ 0.28	\$ (0.31)
Weighted average shares outstanding, basic	52,389,012	44,885,287	50,321,640	44,669,201
Weighted average shares outstanding, diluted	54,709,749	44,885,287	52,315,642	44,669,201

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

	September 30 2018 (1)	December 31 2017 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 60,778	\$ 33,627
Marketable securities	179,801	109,786
Accounts receivable, net	25,259	17,601
Inventory	887	840
Prepaid expenses and other current assets	12,082	8,003
Total current assets	<u>278,807</u>	<u>169,857</u>
Property and equipment, net	4,579	5,306
Intangible assets, net	24,922	26,069
Non-current inventory and other	3,629	4,193
Total assets	<u>\$ 311,937</u>	<u>\$ 205,425</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 19,046	\$ 20,335
Product revenue allowances	27,196	23,028
Milestone obligations under license agreements	—	27,000
Total current liabilities	<u>46,242</u>	<u>70,363</u>
Other non-current liabilities	4,278	3,675
Total liabilities	<u>50,520</u>	<u>74,038</u>
Stockholders' equity:		
Common stock	52	45
Additional paid-in capital	607,873	492,802
Accumulated other comprehensive income (loss)	70	(34)
Accumulated deficit	<u>(346,578)</u>	<u>(361,426)</u>
Total stockholders' equity	<u>261,417</u>	<u>131,387</u>
Total liabilities and stockholders' equity	<u>\$ 311,937</u>	<u>\$ 205,425</u>

- (1) With the adoption of Accounting Standards Codification Subtopic 606, *Revenue from Contracts with Customers*, on January 1, 2018, provision for product returns is included in product revenue allowances and other non-current liabilities in the current year. Provision for product returns is included in accounts receivable, net in the prior year. Please refer to footnote 2 in the quarterly report on Form 10-Q for the quarter ended September 30, 2018, to be filed in the fourth quarter of 2018, for more information.

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

	Three Months Ended		Nine Months Ended	
	September 30 2018	September 30 2017	September 30 2018	September 30 2017
Net income (loss)	\$ 7,171	\$ (4,550)	\$ 14,848	\$ (13,729)
Adjustments:				
Stock-based compensation	2,872	2,771	8,744	7,683
Intangible asset amortization	397	432	1,147	1,318
Non-GAAP Net income (loss)	<u>\$ 10,440</u>	<u>\$ (1,347)</u>	<u>\$ 24,739</u>	<u>\$ (4,728)</u>
Non-GAAP Net income (loss) per share, basic	\$ 0.20	\$ (0.03)	\$ 0.49	\$ (0.11)
Weighted average shares outstanding, basic	52,389,012	44,885,287	50,321,640	44,669,201
Operating expenses	\$ 42,902	\$ 46,259	\$ 127,489	\$ 135,560
Adjustments:				
Cost of goods sold excluding amortization	(5,068)	(4,525)	(14,841)	(13,057)
Stock-based compensation	(2,872)	(2,771)	(8,744)	(7,683)
Intangible asset amortization	(397)	(432)	(1,147)	(1,318)
Non-GAAP Operating expenses excluding Cost of goods sold	<u>\$ 34,565</u>	<u>\$ 38,531</u>	<u>\$ 102,757</u>	<u>\$ 113,502</u>
Research and development	\$ 11,390	\$ 10,178	\$ 30,672	\$ 28,393
Adjustment:				
Stock-based compensation	(326)	(264)	(963)	(958)
Non-GAAP Research and development	<u>\$ 11,064</u>	<u>\$ 9,914</u>	<u>\$ 29,709</u>	<u>\$ 27,435</u>
Selling, general and administrative	\$ 26,047	\$ 31,124	\$ 80,829	\$ 92,792
Adjustment:				
Stock-based compensation	(2,546)	(2,507)	(7,781)	(6,725)
Non-GAAP Selling, general and administrative	<u>\$ 23,501</u>	<u>\$ 28,617</u>	<u>\$ 73,048</u>	<u>\$ 86,067</u>

COMPANY CONTACT:

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

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