



Vanda Pharmaceuticals Reports Third Quarter 2016 Financial Results

November 2, 2016

- Total revenues grew to \$38.5 million, a 7% increase compared to the second quarter of 2016 and a 36% increase compared to the same period in 2015

WASHINGTON, Nov. 2, 2016 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: [VNDA](#)), today announced financial and operational results for the third quarter ended September 30, 2016.

"This quarter marks a significant milestone for Vanda, having secured long-term exclusivity for Fanapt and demonstrated our ability to grow our commercial assets and expand our pipeline of products," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO.

Key Highlights:

- Total net product sales from HETLIOZ[®] and Fanapt[®] were \$38.5 million during the third quarter of 2016, a 7% increase compared to \$36.0 million in the second quarter of 2016 and a 36% increase compared to \$28.3 million in the third quarter of 2015.
- Cash, cash equivalents and marketable securities (Cash) were \$142.6 million as of September 30, 2016, representing an increase to Cash of \$6.6 million in the third quarter of 2016.

HETLIOZ[®] (tasimelteon)

- HETLIOZ[®] net product sales grew to \$18.7 million in the third quarter of 2016, a 7% increase compared to \$17.5 million in the second quarter of 2016 and a 60% increase compared to \$11.7 million in the third quarter of 2015.
- In August 2016, HETLIOZ[®] was made available in Germany, representing the first launch of HETLIOZ[®] outside of the U.S.
- The pharmacokinetic study of the HETLIOZ[®] pediatric formulation is enrolling.
- Enrollment in the Smith-Magenis Syndrome (SMS) open label interventional study is ongoing. Enrollment in the SMS placebo controlled clinical study began in the fourth quarter of 2016.
- The screening of patients for a Jet Lag Disorder clinical study is ongoing. Results from the Jet Lag Disorder study are expected in 2017.

Fanapt[®] (iloperidone)

- Fanapt[®] net product sales grew to \$19.8 million in the third quarter of 2016, a 6% increase compared to \$18.6 million in the second quarter of 2016 and a 19% increase compared to \$16.7 million in the third quarter of 2015.
- In August 2016, the Delaware District Court ruled that Roxane Laboratories, Inc.'s (Roxane) proposed generic version of Fanapt[®] infringed two of Vanda's patents and issued an injunction barring Roxane from marketing its product until November 2, 2027.
- In October 2016, Vanda settled its Fanapt[®] patent litigation against Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd.
- An expansion of the Fanapt[®] U.S. field sales team is now planned for the first quarter 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 ongoing. Results are expected in 2017.
- A tradipitant clinical study for the treatment of gastroparesis is expected to begin enrolling patients in the fourth quarter of 2016. Results are expected in 2017.

Non-GAAP Financial Results

For the third quarter of 2016, Non-GAAP net income was \$4.6 million, compared to a Non-GAAP net loss of \$4.5 million, for the third 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 and expects to achieve the following financial objectives in 2016:

Financial Objectives	2016 Guidance
Combined net product sales from both HETLIOZ [®] and Fanapt [®]	\$143 to \$153 million
HETLIOZ [®] net product sales	\$73 to \$78 million ⁽²⁾
Fanapt [®] net product sales	\$70 to \$75 million
Non-GAAP Operating expenses, excluding Cost of goods sold ⁽¹⁾	\$125 to \$135 million ⁽²⁾
Intangible asset amortization	\$10.9 million
Stock-based compensation	\$8 to \$10 million
Year end 2016 Cash	\$123 to \$143 million ⁽³⁾

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

(2) Results are expected to be at the lower end of the guidance range.

(3) Results are expected to be at the higher end of the guidance range.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, November 2, 2016, at 4:30 PM ET. During the call, Vanda's management will discuss the third 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 43560411. A replay of the call will be available on Wednesday, November 2, 2016, beginning at 7:00 PM ET and will be accessible until Wednesday, November 9, 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 43560411.

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 and quarterly report on Form 10-Q for the quarter ended June 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 quarterly report on Form 10-Q for the quarter ended September 30, 2016, to be filed with the SEC in the fourth 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.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
<i>(\$ in thousands, except per share amounts)</i>				
Revenues:				
HETLIOZ [®] product sales, net	\$ 18,715	\$ 11,682	\$ 52,376	\$ 29,159
Fanapt [®] product sales, net	19,767	16,662	55,397	48,917
Total revenues	<u>38,482</u>	<u>28,344</u>	<u>107,773</u>	<u>78,076</u>
Operating expenses:				
Cost of goods sold	6,990	6,510	19,440	17,291
Research and development	7,294	9,974	21,542	20,398
Selling, general and administrative	21,908	18,458	75,880	55,650
Intangible asset amortization	2,943	2,943	8,828	10,029
Total operating expenses	<u>39,135</u>	<u>37,885</u>	<u>125,690</u>	<u>103,368</u>
Loss from operations	(653)	(9,541)	(17,917)	(25,292)
Other income	223	80	511	225
Net loss	<u>\$ (430)</u>	<u>\$ (9,461)</u>	<u>\$ (17,406)</u>	<u>\$ (25,067)</u>
Net loss per share, basic and diluted	\$ (0.01)	\$ (0.22)	\$ (0.40)	\$ (0.60)
Weighted average shares outstanding, basic and diluted	43,515,404	42,435,405	43,275,074	42,059,839

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30	December 31
	2016	2015
<i>(\$ in thousands)</i>		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,765	\$ 50,843
Marketable securities	109,814	92,337
Accounts receivable, net	15,928	16,331
Inventory	865	1,294
Prepaid expenses and other current assets	11,036	5,742
Total current assets	<u>170,408</u>	<u>166,547</u>
Property and equipment, net	4,731	4,570
Intangible assets, net	29,924	38,752
Non-current inventory and other	3,380	3,181
Total assets	<u>\$ 208,443</u>	<u>\$ 213,050</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	\$ 17,572	\$ 15,767

Accrued government and other rebates	33,109	35,550
Total current liabilities	50,681	51,317
Milestone obligation under license agreement	25,000	25,000
Other non-current liabilities	3,597	3,706
Total liabilities	79,278	80,023
Stockholders' equity:		
Common stock	44	43
Additional paid-in capital	474,234	460,794
Accumulated other comprehensive income	142	39
Accumulated deficit	(345,255)	(327,849)
Total stockholders' equity	129,165	133,027
Total liabilities and stockholders' equity	\$ 208,443	\$ 213,050

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

	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
<i>(in thousands, except for share and per share amounts)</i>				
Net loss	\$ (430)	\$ (9,461)	\$ (17,406)	\$ (25,067)
Adjustments:				
Stock-based compensation	2,100	2,061	6,440	6,074
Intangible asset amortization	2,943	2,943	8,828	10,029
Non-GAAP Net income (loss)	<u>\$ 4,613</u>	<u>\$ (4,457)</u>	<u>\$ (2,138)</u>	<u>\$ (8,964)</u>
Non-GAAP Net income (loss) per share, basic	\$ 0.11	\$ (0.11)	\$ (0.05)	\$ (0.21)
Weighted average shares outstanding, basic	43,515,404	42,435,405	43,275,074	42,059,839
Operating expenses	\$ 39,135	\$ 37,885	\$ 125,690	\$ 103,368
Adjustments:				
Cost of goods sold	(6,990)	(6,510)	(19,440)	(17,291)
Stock-based compensation	(2,100)	(2,061)	(6,440)	(6,074)
Intangible asset amortization	(2,943)	(2,943)	(8,828)	(10,029)
Non-GAAP Operating expenses excluding Cost of goods sold	<u>\$ 27,102</u>	<u>\$ 26,371</u>	<u>\$ 90,982</u>	<u>\$ 69,974</u>
Research and development	\$ 7,294	\$ 9,974	\$ 21,542	\$ 20,398
Adjustment:				
Stock-based compensation	(539)	(516)	(1,552)	(1,743)
Non-GAAP Research and development	<u>\$ 6,755</u>	<u>\$ 9,458</u>	<u>\$ 19,990</u>	<u>\$ 18,655</u>
Selling, general and administrative	\$ 21,908	\$ 18,458	\$ 75,880	\$ 55,650
Adjustment:				
Stock-based compensation	(1,561)	(1,545)	(4,888)	(4,331)
Non-GAAP Selling, general and administrative	<u>\$ 20,347</u>	<u>\$ 16,913</u>	<u>\$ 70,992</u>	<u>\$ 51,319</u>

COMPANY CONTACT:

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

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-third-quarter-2016-financial-results-300356088.html>

SOURCE Vanda Pharmaceuticals Inc.