

Vanda Pharmaceuticals Reports First Quarter 2016 Financial Results

May 4, 2016

- HETLIOZ® net product sales grew to \$16.2 million in the first quarter 2016
- Fanapt® net product sales grew to \$17.1 million in the first quarter 2016
- Vanda reiterates 2016 net product sales guidance of \$143 million to \$153 million

WASHINGTON, May 4, 2016 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: <u>VNDA</u>), today announced financial and operational results for the first quarter ended March 31, 2016.

"Vanda made significant progress in the first quarter of 2016," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "We continued to grow our HETLIOZ and Fanapt franchises and we look forward to a number of important clinical development milestones in the coming months."

Key Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were \$33.3 million during the first quarter of 2016, a 4% increase compared to \$31.8 million in the fourth quarter of 2015 and a 50% increase compared to \$22.2 million the first quarter of 2015.
- In April 2016, Gian Piero Reverberi was named Senior Vice President, Chief Commercial Officer.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$16.2 million in the first quarter of 2016, a 7% increase compared to \$15.1 million in the fourth quarter of 2015 and a 117% increase compared to \$7.5 million in the first 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. A 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.
- A Jet Lag Disorder Phase II proof of concept study is planned for the second half of 2016 leading to an expected Phase III
 program in 2017.

Fanapt® (iloperidone)

- Fanapt[®] net product sales were \$17.1 million for the first quarter of 2016, a 2% increase compared to \$16.7 million in the fourth quarter of 2015 and a 16% increase compared to \$14.7 million in the first quarter of 2015.
- The U.S. Food and Drug Administration (FDA) review of the supplemental New Drug Application for Fanapt[®] that includes data for the maintenance treatment of schizophrenia in adults is ongoing. The FDA has set a PDUFA goal date of May 27, 2016.

Tradipitant

• Enrollment began in the first quarter of 2016 for a tradipitant Phase II proof of concept study for the treatment of chronic pruritus in patients with atopic dermatitis.

Cash, cash equivalents and marketable securities (Cash) were \$138.3 million as of March 31, 2016, representing a decrease to Cash of \$4.9 million in the first quarter of 2016.

Non-GAAP Financial Results

For the first quarter of 2016, Non-GAAP net loss was \$7.1 million, or \$0.17 per share, compared to a Non-GAAP net loss of \$4.1 million, or \$0.10 per share, for the first 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:

- 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 \$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, May 4, 2016, at 4:30 PM ET. During the call, Vanda's management will discuss the first 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 42335557. A replay of the call will be available on Wednesday, May 4, 2016, beginning at 7:00 PM ET and will be accessible until Wednesday, May 11, 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 42335557.

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 March 31, 2016, to be filed with the SEC in the second 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.

	Three Months Ended			
	N	larch 31	March 31	
(in thousands, except for share and per share amounts)	_	2016	2015	
Revenues:				
HETLIOZ [®] product sales, net	\$	16,201\$	7,460	
Fanapt [®] product sales, net		17,061	14,690	
Total revenues		33,262	22,150	
Operating expenses: Cost of goods sold Research and development Selling, general and administrative Intangible asset amortization Total operating expenses	_	5,956 7,548 29,290 2,943 45,737	5,015 4,478 18,806 4,144 32,443	
Loss from operations Other income Net loss	\$	(12,475) 117 (12,358)\$	(10,293) 72 (10,221)	
Net loss per share, basic and diluted	\$	(0.29)\$	(0.24)	

Weighted average shares outstanding, basic and diluted 43,104,462 41,744,948

VANDA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31 D		
(\$ in thousands)	_	2016	2015
ASSETS			
Current assets:	•	00 740 0	50.040
Cash and cash equivalents	\$	38,740\$	50,843
Marketable securities		99,590	92,337
Accounts receivable, net		16,679	16,331
Inventory		938	1,294
Prepaid expenses and other current assets	_	6,502	5,742
Total current assets		162,449	166,547
Property and equipment, net		4,351	4,570
Intangible assets, net		35,809	38,752
Non-current inventory and other	_	4,131	3,181
Total assets	\$	206,740\$	213,050
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:			
Accounts payable and accrued liabilities	\$	22,664\$	15,767
Accrued government and other rebates	_	32,376	35,550
Total current liabilities		55,040	51,317
Milestone obligation under license agreement		25,000	25,000
Other non-current liabilities	_	3,688	3,706
Total liabilities		83,728	80,023
Stockholders' equity:			
Common stock		43	43
Additional paid-in capital		463,084	460,794
Accumulated other comprehensive income		92	39
Accumulated deficit	_(340,207)	(327,849)
Total stockholders' equity		123,012	133,027
Total liabilities and stockholders' equity	\$	206,740\$	213,050

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

	Three Months Ended		
	March 31		March 31
(in thousands, except for share and per share amounts)	_	2016	2015
Net loss Adjustments:	\$	(12,358)	\$ (10,221)
Stock-based compensation		2,266 2,943	1,945 4,144
Intangible asset amortization Non-GAAP Net loss	\$	(7,149)	
Non-GAAP Net loss per share, basic and diluted	\$	(0.17)	\$ (0.10)
Weighted average shares outstanding, basic and diluted	۱ ،	43,104,462	41,744,948
Operating expenses Adjustments:	\$	45,737	\$ 32,443
Cost of goods sold		(5,956)	(5,015)
Stock-based compensation		(2,266)	(1,945)
Intangible asset amortization	_	(2,943)	(4,144)
Non-GAAP Operating expenses excluding Cost of goods sold	\$	34,572	\$ 21,339
Research and development Adjustment:	\$	7,548	\$ 4,478
Stock-based compensation		(524)	(624)
Non-GAAP Research and development	\$	7,024	\$ 3,854
Selling, general and administrative Adjustment:	\$	29,290	\$ 18,806
Stock-based compensation	_	(1,742)	(1,321)
Non-GAAP Selling, general and administrative	\$	27,5489	17,485

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To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-first-quarter-2016-financial-results-300262969.html

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