



Vanda Pharmaceuticals Reports Fourth Quarter 2015 and Full Year 2015 Financial Results

February 10, 2016

- **HETLIOZ® net product sales grew to \$15.1 million in the fourth quarter 2015**
- **Full year 2015 total revenues grew to \$109.9 million**

WASHINGTON, Feb. 10, 2016 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the fourth quarter and full year ended December 31, 2015.

"2015 was a transformational year for Vanda with the continued growth of HETLIOZ in the U.S., and the European market approval of HETLIOZ for Non-24," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "The addition of Fanapt to our U.S. product portfolio builds on this success and underscores Vanda's commitment to bringing important treatment options to patients."

Key Highlights:

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to \$15.1 million in the fourth quarter of 2015, a 30% increase compared to \$11.7 million in the third quarter of 2015 and a 152% increase compared to \$6.0 million reported in the fourth quarter of 2014.
- HETLIOZ® net product sales were \$44.3 million for the full year 2015, a 246% increase compared to \$12.8 million reported for the full year 2014.
- During the fourth quarter of 2015, Vanda initiated an open label interventional study of tasimelteon for the treatment of Smith-Magenis Syndrome. A placebo controlled, Phase III study is planned to begin in the second half of 2016.
- During the fourth quarter of 2015, Vanda completed an observational study of Jet Lag Disorder. A placebo controlled, Phase III study is planned to begin in the second half of 2016.

Fanapt® (iloperidone)

- Fanapt® net product sales were \$16.7 million for the fourth quarter of 2015, compared to \$16.7 million in the third quarter of 2015.
- Fanapt® net product sales were \$65.6 million for the full year 2015, compared to \$65.0 million in 2014, as reported by Novartis AG.
- In December 2015, the Marketing Authorization Application for oral Fanaptum® tablets was accepted for evaluation by the European Medicines Agency for the treatment of schizophrenia in adults.
- The FDA review of the supplemental New Drug Application for Fanapt® for the maintenance treatment of schizophrenia in adults is ongoing. The FDA has set a PDUFA goal date in May 2016.

Cash, cash equivalents and marketable securities (Cash) were \$143.2 million as of December 31, 2015, representing an increase to Cash of \$13.4 million in 2015.

Non-GAAP Financial Results

Vanda Non-GAAP total revenues for the fourth quarter of 2015 were \$31.8 million, an increase of 319% compared to Non-GAAP total revenues of \$7.6 million for the fourth quarter of 2014. Vanda Non-GAAP total revenues for the full year 2015 were \$109.9 million, an increase of 466% compared to Non-GAAP total revenues of \$19.4 million for the full year 2014.

For the fourth quarter of 2015, Non-GAAP net loss was \$10.0 million, or \$0.23 per share, compared to a Non-GAAP net loss of \$13.5 million, or \$0.36 per share, for the fourth quarter of 2014. Vanda Non-GAAP net loss was \$18.9 million for the full year 2015, compared to a Non-GAAP net loss of \$80.0 million for the full year 2014. Non-GAAP Diluted net loss per share for the full year 2015 was \$0.45, compared to a Non-GAAP Diluted net loss per share of \$2.30 for the full year 2014.

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."

2016 Financial Guidance

Vanda expects to achieve the following financial objectives in 2016:

- Net product sales from both HETLIOZ® and Fanapt® of between \$143 and \$153 million.
- HETLIOZ® net product sales of between \$73 and \$78 million.
- 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. The primary drivers of the expected increase over the prior year are investments in the U.S. Fanapt® and European HETLIOZ® commercial

businesses.

- Non-GAAP Operating expenses also 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 million and \$143 million.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, February 10, 2016, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2015 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 41672752. A replay of the call will be available on Wednesday, February 10, 2016, beginning at 7:00 PM ET and will be accessible until Wednesday, February 17, 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 41672752.

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 Total revenues" excludes the Fanapt® licensing agreement revenue. 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 Fanapt® licensing revenue, stock based compensation, intangible asset amortization and gain on arbitration settlement.

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 Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of novel therapies addressing high unmet medical needs. For more on Vanda, 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, 2014 and quarterly report on Form 10-Q for the quarter ended September 30, 2015, 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, 2015, to be filed with the SEC in the first 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		Year Ended	
	December 31	December 31	December 31	December 31
<i>(in thousands, except for share and per share amounts)</i>	2015	2014	2015	2014
Revenues:				
HETLIOZ® product sales, net	\$ 15,143	\$ 6,021	\$ 44,302	\$ 12,802
Fanapt® product sales, net	16,706	-	65,623	107
Fanapt® royalty revenue	-	1,584	-	6,502
Fanapt® licensing revenue	-	7,765	-	30,746
Total revenues	31,849	15,370	109,925	50,157
Operating expenses:				
Cost of goods sold	6,171	682	23,462	1,583
Research and development	8,747	4,752	29,145	19,230
Selling, general and administrative	28,881	17,323	84,531	84,644
Intangible asset amortization	2,943	536	12,972	2,254
Gain on arbitration settlement	-	(77,616)	-	(77,616)
Total operating expenses	46,742	(54,323)	150,110	30,095
Income (loss) from operations	(14,893)	69,693	(40,185)	20,062
Other income	95	26	320	124
Net income (loss)	<u>\$ (14,798)</u>	<u>\$ 69,719</u>	<u>\$ (39,865)</u>	<u>\$ 20,186</u>
Net income (loss) per share:				
Basic	\$ (0.35)	\$ 1.85	\$ (0.94)	\$ 0.58
Diluted	\$ (0.35)	\$ 1.77	\$ (0.94)	\$ 0.55
Weighted average shares outstanding:				
Basic	42,815,291	37,622,884	42,250,254	34,774,163
Diluted	42,815,291	39,421,014	42,250,254	36,686,723

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	December 31, December 31,	
<i>(\$ in thousands)</i>	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 50,843	\$ 60,901
Marketable securities	92,337	68,921
Accounts receivable, net	16,331	3,654
Inventory	1,294	5,170
Prepaid expenses and other current assets	5,742	3,084
Total current assets	166,547	141,730
Property and equipment, net	4,570	2,437
Intangible assets, net	38,752	26,724
Non-current inventory and other	3,181	813
Total assets	<u>\$ 213,050</u>	<u>\$ 171,704</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 15,767	\$ 7,291
Accrued government and other rebates	35,550	495
Total current liabilities	51,317	7,786
Milestone obligation under license agreement	25,000	-
Other non-current liabilities	3,706	3,101
Total liabilities	80,023	10,887
Stockholders' equity:		

Common stock	43	41
Additional paid-in capital	460,794	448,744
Accumulated other comprehensive income	39	16
Accumulated deficit	(327,849)	(287,984)
Total stockholders' equity	133,027	160,817
Total liabilities and stockholders' equity	<u>\$ 213,050</u>	<u>\$ 171,704</u>

Reconciliation of GAAP to Non-GAAP Financial Information

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

	Three Months Ended		Year Ended	
	December 31	December 31	December 31	December 31
(in thousands, except for share and per share amounts)	2015	2014	2015	2014
Net income (loss)	\$ (14,798)	\$ 69,719	\$ (39,865)	\$ 20,186
Adjustments:				
Fanapt® licensing revenue	-	(7,765)	-	(30,746)
Stock-based compensation	1,887	1,631	7,961	5,878
Intangible asset amortization	2,943	536	12,972	2,254
Gain on arbitration settlement	-	(77,616)	-	(77,616)
Non-GAAP Net loss	<u>\$ (9,968)</u>	<u>\$ (13,495)</u>	<u>\$ (18,932)</u>	<u>\$ (80,044)</u>
Non-GAAP Net loss per share:				
Basic & Diluted	\$ (0.23)	\$ (0.36)	\$ (0.45)	\$ (2.30)
Weighted average shares outstanding:				
Basic & Diluted	42,815,291	37,622,884	42,250,254	34,774,163
Total revenues	\$ 31,849	\$ 15,370	\$ 109,925	\$ 50,157
Adjustment:				
Fanapt® licensing revenue	-	(7,765)	-	(30,746)
Non-GAAP Total revenues	<u>\$ 31,849</u>	<u>\$ 7,605</u>	<u>\$ 109,925</u>	<u>\$ 19,411</u>
Operating expenses	\$ 46,742	\$ (54,323)	\$ 150,110	\$ 30,095
Adjustments:				
Cost of goods sold	(6,171)	(682)	(23,462)	(1,583)
Stock-based compensation	(1,887)	(1,631)	(7,961)	(5,878)
Intangible asset amortization	(2,943)	(536)	(12,972)	(2,254)
Gain on arbitration settlement	-	77,616	-	77,616
Non-GAAP Operating expenses	<u>\$ 35,741</u>	<u>\$ 20,444</u>	<u>\$ 105,715</u>	<u>\$ 97,996</u>
Research and development	\$ 8,747	\$ 4,752	\$ 29,145	\$ 19,230
Adjustment:				
Stock-based compensation	(526)	(556)	(2,269)	(1,933)
Non-GAAP Research and development	<u>\$ 8,221</u>	<u>\$ 4,196</u>	<u>\$ 26,876</u>	<u>\$ 17,297</u>
Selling, general and administrative	\$ 28,881	\$ 17,323	\$ 84,531	\$ 84,644
Adjustment:				
Stock-based compensation	(1,361)	(1,075)	(5,692)	(3,945)
Non-GAAP Selling, general and administrative	<u>\$ 27,520</u>	<u>\$ 16,248</u>	<u>\$ 78,839</u>	<u>\$ 80,699</u>

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