



Vanda Pharmaceuticals Reports Second Quarter 2015 Financial Results

July 29, 2015

- **HETLIOZ® U.S. net product sales increased by 34% over the prior quarter to \$10.0 million**
 - **Fanapt® U.S. net product sales increased by 20% over the prior quarter to \$17.6 million**
 - **Vanda raises its full year net product sales guidance to between \$100 million and \$115 million**
- Conference call scheduled for 4:30 p.m. ET today**

WASHINGTON, July 29, 2015 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the second quarter ended June 30, 2015.

"We are impressed with U.S. sales performance for both HETLIOZ and Fanapt" said Mihael H. Polymeropoulos M.D., Vanda's President and CEO, "further investments in the commercialization and life cycle management of our products set the stage for the next level of growth for Vanda."

Financial Highlights

- Total net product sales for the second quarter of 2015 increased by 25% over the prior quarter to \$27.6 million.
- A net loss of \$5.4 million, or \$0.13 per share, was recorded for the second quarter of 2015. This reflects a 75% decrease compared with a net loss of \$21.6 million, or \$0.64 per share, for the same period in 2014.
- Cash, cash equivalents and marketable securities grew to \$146.6 million as of June 30, 2015.

HETLIOZ® (tasimelteon)

- HETLIOZ® U.S. net product sales grew to \$10.0 million in the second quarter of 2015, a 34% increase compared to \$7.5 million in the first quarter of 2015.
- In July 2015, the European Commission approved HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in totally blind adults in the European Union (EU).
- HETLIOZ® life cycle management activities continue to progress with plans to initiate a Phase III study of HETLIOZ® for the treatment of jet lag during 2015.
- A HETLIOZ® interventional study for the treatment of Smith-Magenis Syndrome is expected to begin during the fourth quarter of 2015.
- During July 2015, HETLIOZ® patent number 9,060,995 ('995) was listed in the U.S. Food and Drug Administration's (FDA) Orange Book. The '995 patent expires in January 2033.

Fanapt® (iloperidone)

- Fanapt® U.S. net product sales grew to \$17.6 million in the second quarter of 2015, a 20% increase compared to \$14.7 million in the first quarter of 2015.
- Vanda expects to file a supplemental New Drug Application for Fanapt® with the FDA in the second half of 2015 to include the results from the long-term maintenance REPRIEVE clinical study in the Fanapt® package insert.
- Vanda expects to file for European regulatory approval of oral Fanapt® in the second half of 2015.

Tradipitant (VLY-686)

- Vanda expects to initiate a Phase II study in chronic pruritus in patients with atopic dermatitis in the fourth quarter of 2015, seeking to confirm the exploratory efficacy findings reported in the Phase II proof of concept study (2101).

Non-GAAP Financial Results

Vanda Non-GAAP total revenues for the second quarter of 2015 were \$27.6 million, compared to Non-GAAP total revenues of \$3.1 million for the second quarter of 2014.

For the second quarter of 2015, Non-GAAP net loss was \$0.4 million, or \$0.01 per share, compared with a Non-GAAP net loss of \$27.3 million, or \$0.81 per share, for the same period in 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".

2015 Financial Guidance

Vanda is updating its 2015 financial guidance and expects to achieve the following financial objectives in 2015:

- Combined net product sales from both HETLIOZ[®] and Fanapt[®] of between \$100 million and \$115 million, compared to prior guidance of \$95 million to \$110 million.
- HETLIOZ[®] net product sales of between \$40 million to \$45 million.
- Fanapt[®] net product sales of between \$60 million to \$70 million, compared to prior guidance of \$55 million to \$65 million.
- Non-GAAP Operating expenses, excluding cost of goods sold, of between \$100 million and \$110 million, compared to prior guidance of \$105 million to \$120 million.

Non-GAAP Operating expenses also excludes:

- Intangible asset amortization expense of \$13.0 million.
- Stock-based compensation of between \$8.5 million and \$10.5 million.

Full U.S. HETLIOZ[®] Prescribing Information can be found at: www.hetlio.com.

Full U.S. Fanapt[®] Prescribing Information, including Boxed Warnings and Important Safety Information can be found at: www.fanapt.com.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, July 29, 2015, at 4:30 PM ET. During the call, Vanda's management will discuss the second quarter 2015 financial results and other corporate activities. Investors can call 1-800-708-4539 (domestic) or 1-847-619-6396 (international) and use passcode 40193344. A replay of the call will be available beginning Wednesday, July 29, 2015 at 7:00 PM ET and will be accessible until Wednesday August 5, 2015, 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 40193344.

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 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 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)" and "Non-GAAP net income (loss) per share" excludes the 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 2015 Non-GAAP Operating expenses, excluding cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2015 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 the 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 products for the treatment of central nervous system disorders. For more on Vanda, please visit www.vandapharma.com.

Forward-Looking Statements

Various statements in this release, including, but not limited to, the guidance provided in the heading of this press release and under "2015 Financial Guidance" above, and statements regarding Vanda's clinical plans for HETLIOZ[®] and Tradipitant and Vanda's U.S. and EU regulatory strategy for Fanapt[®], are "forward-looking statements" under the securities laws. 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 ability to successfully commercialize HETLIOZ[®] for the treatment of Non-24 in the U.S. and Europe; uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ[®]; Vanda's ability to generate U.S. sales of Fanapt[®] for the treatment of schizophrenia; the timing and costs of Vanda's establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt[®] in the U.S.; Vanda's dependence on third-party manufacturers to manufacture HETLIOZ[®]

and Fanapt® in sufficient quantities and quality; Vanda's limited sales and marketing infrastructure; the regulatory status of Fanapt® in Europe; Vanda's ability to successfully commercialize HETLIOZ® and Fanapt® outside the U.S.; Vanda's ability to defend and enforce any patent claims and other intellectual property rights; Vanda's ability to obtain the capital necessary to fund its research and development or commercial activities; the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the FDA's approval of Fanapt®; delays in the completion of Vanda's or its partners' clinical trials; a failure of Vanda's products to be demonstrably safe and effective; Vanda's expectations regarding trends with respect to its revenues, costs, expenses and liabilities; Vanda's failure to identify or obtain rights to new products; a loss of any of Vanda's key scientists or management personnel; limitations on Vanda's ability to utilize some or all of its prior net operating losses and orphan drug and research and development credits; the costs and effects of litigation; losses incurred from product liability claims made against Vanda; 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, 2014 and quarterly report on Form 10-Q for the quarter ended March 31, 2015 which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may also be set forth in those sections of Vanda's quarterly report on Form 10-Q for the quarter ended June 30, 2015, to be filed with the SEC in the third quarter of 2015. 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 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

	Three Months Ended		Six Months Ended	
	June 30 2015	June 30 2014	June 30 2015	June 30 2014
(\$ in thousands, except per share amounts)				
Revenues:				
HETLIOZ® product sales, net	\$ 10,017	\$ 1,559	\$ 17,477	\$ 1,559
Fanapt® product sales, net	17,565	-	32,255	-
Fanapt® royalty revenue	-	1,539	-	3,230
Fanapt® licensing revenue	-	7,764	-	15,216
Total revenues	27,582	10,862	49,732	20,005
Operating expenses:				
Cost of goods sold	5,766	198	10,781	198
Research and development	5,946	3,514	10,424	10,777
Selling, general and administrative	18,386	28,139	37,192	56,032
Intangible asset amortization	2,942	617	7,086	1,182
Total operating expenses	33,040	32,468	65,483	68,189
Income (loss) from operations	(5,458)	(21,606)	(15,751)	(48,184)
Other income	72	31	144	76
Net income (loss)	<u>\$ (5,386)</u>	<u>\$ (21,575)</u>	<u>\$ (15,607)</u>	<u>\$ (48,108)</u>
Net income (loss) per share:				
Basic and diluted	\$ (0.13)	\$ (0.64)	\$ (0.37)	\$ (1.42)

Weighted average shares outstanding:

Basic and diluted	41,991,578	33,874,625	41,868,944	33,777,207
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**VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS**

	June 30, December 31,	
(\$ in thousands)	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 48,337	\$ 60,901
Marketable securities	98,300	68,921
Accounts receivable, net	15,818	3,654
Inventory	4,962	5,170
Prepaid expenses and other current assets	6,956	3,084
Total current assets	174,373	141,730
Property and equipment, net	3,869	2,437
Intangible assets, net	44,638	26,724
Restricted cash and other	813	813
Total assets	<u>\$ 223,693</u>	<u>\$ 171,704</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 1,631	\$ 835
Accrued and other current liabilities	43,562	6,951
Total current liabilities	45,193	7,786
Milestone obligation under license agreement	25,000	-
Other non-current liabilities	3,753	3,101
Total liabilities	73,946	10,887
Stockholders' equity:		
Common stock	42	41
Additional paid-in capital	453,269	448,744
Accumulated other comprehensive income	27	16
Accumulated deficit	(303,591)	(287,984)
Total stockholders' equity	149,747	160,817
Total liabilities and stockholders' equity	<u>\$ 223,693</u>	<u>\$ 171,704</u>

Reconciliation of GAAP to Non-GAAP Financial Information

**VANDA PHARMACEUTICALS INC.
Reconciliation of GAAP to Non-GAAP Financial Information**

	Three Months Ended		Six Months Ended	
(\$ in thousands, except per share amounts)	June 30 2015	June 30 2014	June 30 2015	June 30 2014
Net income (loss)	\$ (5,386)	\$ (21,575)	\$ (15,607)	\$ (48,108)
Adjustments:				
Fanapt® licensing revenue	-	(7,764)	-	(15,216)
Stock-based compensation	2,068	1,443	4,013	2,836
Intangible asset amortization	2,942	617	7,086	1,182

Non-GAAP Net income (loss)	\$	(376)	\$	(27,279)	\$	(4,508)	\$	(59,306)
Non-GAAP Net income (loss) per share:								
Basic and diluted	\$	(0.01)	\$	(0.81)	\$	(0.11)	\$	(1.76)
Weighted average shares outstanding:								
Basic and diluted		41,991,578		33,874,625		41,868,944		33,777,207
Total revenues	\$	27,582	\$	10,862	\$	49,732	\$	20,005
Adjustment:								
Fanapt® licensing revenue		-		(7,764)		-		(15,216)
Non-GAAP Total revenues	\$	27,582	\$	3,098	\$	49,732	\$	4,789
Operating expenses	\$	33,040	\$	32,468	\$	65,483	\$	68,189
Adjustments:								
Cost of goods sold		(5,766)		(198)		(10,781)		(198)
Stock-based compensation		(2,068)		(1,443)		(4,013)		(2,836)
Intangible asset amortization		(2,942)		(617)		(7,086)		(1,182)
Non-GAAP Operating expenses excluding Cost of goods sold	\$	22,264	\$	30,210	\$	43,603	\$	63,973
Research and development	\$	5,946	\$	3,514	\$	10,424	\$	10,777
Adjustment:								
Stock-based compensation		(603)		(454)		(1,227)		(935)
Non-GAAP Research and development	\$	5,343	\$	3,060	\$	9,197	\$	9,842
Selling, general and administrative	\$	18,386	\$	28,139	\$	37,192	\$	56,032
Adjustment:								
Stock-based compensation		(1,465)		(989)		(2,786)		(1,901)
Non-GAAP Selling, general and administrative	\$	16,921	\$	27,150	\$	34,406	\$	54,131

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