



## Vanda Pharmaceuticals Reports Fourth Quarter 2014 and Full Year 2014 Financial Results

February 19, 2015

- **HETLIOZ® net product sales in the U.S. grew to \$6.0 million in the fourth quarter of 2014, a 15% increase as compared to the third quarter of 2014.**
- **Vanda expects HETLIOZ® net product sales for 2015 to grow to between \$40 and \$45 million.**
- **Combined 2015 net product sales from both HETLIOZ® and Fanapt® are expected to be between \$95 million and \$110 million.**

WASHINGTON, Feb. 19, 2015 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA), today announced financial and operational results for the fourth quarter and full year ended December 31, 2014.

"2014 was a transformational year for Vanda with the HETLIOZ launch in the U.S. for the treatment of Non-24-Hour Sleep-Wake Disorder. We are impressed with the continued growth of HETLIOZ and are fortunate to be able to offer this important treatment option for patients" said Mihael H. Polymeropoulos M.D., Vanda's President and CEO. "The return of the U.S. and Canadian commercial rights to Fanapt brings an immediately accretive product to Vanda further strengthening our U.S. commercial portfolio."

### Key Highlights:

#### HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales in the U.S. grew to \$6.0 million in the fourth quarter of 2014, a 15% increase, compared to \$5.2 million in the third quarter of 2014. HETLIOZ® net product sales were \$12.8 million for the full year 2014.
- Since the U.S. commercial launch of HETLIOZ® in April 2014, over 760 new patient prescriptions have been written including over 220 in the fourth quarter of 2014. As of December 31, 2014, over 470 patients had initiated HETLIOZ® treatment and over 330 patients were on active treatment reflecting a cumulative persistence rate of approximately 70%.
- The HETLIOZ® Marketing Authorization Application in the European Union (EU) is under review with a regulatory decision expected in the third quarter of 2015.
- Tasimelteon life cycle management activities are ongoing and include a Smith-Magenis Syndrome observational study with results expected in the first half of 2015 and preparations for a clinical development program for pediatric Non-24.
- HETLIOZ® exclusivity in the U.S. is protected by orphan exclusivity and two patents listed in the FDA Orange Book (Orphan exclusivity expiry in 2021; Patent No. 5,856,529 expiry expected in 2022 and Patent No. 8,785,492 expiry in 2033).

#### Fanapt® (loperidone)

- Fanapt® royalty revenue was \$1.6 million for the fourth quarter of 2014, compared to \$1.7 million in the third quarter of 2014. Fanapt® royalty revenue was \$6.5 million for the full year 2014, compared to \$7.1 million for 2013.
- For the full year 2014, Fanapt® U.S. net product sales were \$65.0 million, as reported by Novartis AG (Novartis). Fanapt® U.S. prescriptions for the fourth quarter of 2014 were approximately 40,500, as reported by IMS.
- On December 31, 2014, the Fanapt® U.S. and Canadian rights were returned to Vanda as part of the settlement of arbitration with Novartis.
- Fanapt® exclusivity in the U.S. is protected by two patents listed in the FDA Orange Book (Patent No. RE39198 expiry in 2016 and Patent No. 8,586,610 expiry in 2027).

#### VL-686 (trapidant)

- Results of the Phase II study (2101) of trapidant, an NK1 receptor antagonist, in patients with chronic pruritus are expected in the first quarter of 2015.

### Financial Results for the Fourth Quarter and Full Year 2014

Vanda total revenues for the fourth quarter of 2014 were \$15.4 million, compared to \$8.8 million for the fourth quarter of 2013. Vanda total revenues for the full year 2014 were \$50.2 million, compared to \$33.9 million for 2013.

Selling, general and administrative expenses were \$17.3 million in the fourth quarter of 2014, compared to \$9.9 million in the fourth quarter of 2013. Selling, general and administrative expenses were \$84.6 million in the full year 2014, compared to \$25.1 million in 2013. The increases in selling, general and administrative expenses in fourth quarter and full year 2014 were the result of the U.S. commercial launch support for HETLIOZ®.

Research and development expenses were \$4.8 million in the fourth quarter of 2014, compared to \$6.3 million in the fourth quarter of 2013. Research and development expenses were \$19.2 million in the full year 2014, compared to \$28.5 million in 2013.

Vanda recorded a \$77.6 million gain related to the Novartis arbitration settlement in the fourth quarter of 2014.

Vanda net income was \$69.7 million for the fourth quarter of 2014, compared to a net loss of \$7.7 million for the fourth quarter of 2013. Diluted net income per share for the fourth quarter of 2014 was \$1.77, compared to a net loss per share of \$0.23 for the fourth quarter of 2013. Vanda net income was \$20.2 million for the full year 2014, compared to a net loss of \$21.1 million for 2013. Diluted net income per share for the full year 2014 was \$0.55, compared to a net loss per share of \$0.69 for 2013.

In October 2014, Vanda completed a public common stock offering that resulted in \$62.3 million in net proceeds. In December 2014, Vanda sold \$25.0 million of common stock to Novartis as part of the arbitration settlement. Cash, cash equivalents and marketable securities were \$129.8 million as of December 31, 2014.

### **Non-GAAP Financial Results**

Vanda Non-GAAP Total revenues for the fourth quarter of 2014 were \$7.6 million, compared to \$2.0 million for the fourth quarter of 2013. Vanda Non-GAAP Total revenues for the full year 2014 were \$19.4 million, compared to \$7.1 million for 2013.

Vanda Non-GAAP Net loss was \$13.5 million for the fourth quarter of 2014, compared to a net loss of \$12.7 million for the fourth quarter of 2013. Non-GAAP Diluted net loss per share for the fourth quarter of 2014 was \$0.36, compared to a net loss per share of \$0.38 for the fourth quarter of 2013. Vanda Non-GAAP net loss was \$80.0 million for the full year 2014, compared to a net loss of \$40.9 million for 2013. Non-GAAP Diluted net loss per share for the full year 2014 was \$2.30, compared to a net loss per share of \$1.35 for 2013.

Vanda provides Non-GAAP financial information, which it believe 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 expects to achieve the following financial objectives in 2015:

- Combined net product sales from both HETLIOZ<sup>®</sup> and Fanapt<sup>®</sup> of between \$95 million and \$110 million.
- HETLIOZ<sup>®</sup> net product sales of between \$40 million to \$45 million and Fanapt<sup>®</sup> net product sales of between \$55 million to \$65 million.
- Non-GAAP Operating expenses, excluding cost of sales, of between \$105 million and \$120 million.

In addition, for reporting periods beginning in 2015, Vanda will no longer record Fanapt<sup>®</sup> licensing agreement revenues and will no longer report the number of HETLIOZ<sup>®</sup> prescriptions written, dispensed or patients on therapy.

Full HETLIOZ<sup>®</sup> Prescribing Information can be found at: [www.hetlizio.com](http://www.hetlizio.com).

Full Fanapt<sup>®</sup> Prescribing Information, including Boxed Warnings and Important Safety Information can be found at: [www.fanapt.com](http://www.fanapt.com).

### **Conference Call**

Vanda has scheduled a conference call for today, Thursday, February 19, 2015, at 10:00 AM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2014 financial results and other corporate activities. Investors can call 1-800-708-4540 (domestic) or 1-847-619-6397 (international) and use passcode 38933858. A replay of the call will be available beginning Thursday, February 19, 2015 at 12:30 PM ET and will be accessible until Thursday, February 26, 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 38933858.

The conference call will be broadcast simultaneously on Vanda's website, [www.vandapharma.com](http://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 the Company's business and reflect how it manages the business internally and sets operational goals. Vanda's "Non-GAAP revenues" excludes the Fanapt<sup>®</sup> licensing agreement revenue. The Company's "Non-GAAP G&A expenses" and "Non-GAAP R&D expenses" exclude stock based compensation. "Non-GAAP net income (loss)" and "Non-GAAP Diluted net income (loss) per share" excludes the Fanapt<sup>®</sup> licensing agreement 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 and the Company's use of financial resources and the Company's long-term performance.

This press release includes Non-GAAP Operating expenses, a forward-looking Non-GAAP financial measures under the heading "2015 Financial Guidance". This Non-GAAP financial measures was determined by excluding cost of sales, stock based compensation and intangible asset amortization. We are unable to reconcile this Non-GAAP guidance to GAAP because it is difficult to predict the future impact of these adjustment.

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 products for the treatment of central nervous system disorders. For more on Vanda, please visit [www.vandapharma.com](http://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, 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 the company's forward-looking statements include, among others: Vanda's ability to successfully commercialize HETLIOZ<sup>®</sup> for the treatment of Non-24 in the U.S., uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ<sup>®</sup>, Vanda's dependence on third-party manufacturers to manufacture HETLIOZ<sup>®</sup> in sufficient quantities and quality, Vanda's limited sales and marketing infrastructure, the regulatory status of HETLIOZ<sup>®</sup> in Europe, Vanda's and its partners' ability to successfully commercialize Fanapt<sup>®</sup> in the U.S., Israel and Mexico, the results of Vanda's clinical development activities with respect to Non-24 in children, SMS and chronic pruritus; 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 potential litigation; losses incurred from product liability claims made against Vanda 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, 2013 which is on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov) and Vanda's annual report on Form 10-K for the year ended December 31, 2014 to be filed with the SEC. 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		Twelve Months Ended	
	December 31,	December 31,	December 31,	December 31,
(\$ in thousands, except per share amounts)	2014	2013 <sup>(1)</sup>	2014	2013 <sup>(1)</sup>
Revenues:				
HETLIOZ <sup>®</sup> product revenue, net	\$ 6,021	\$ -	\$ 12,802	\$ -
Fanapt <sup>®</sup> product revenue, net	-	-	107	-
Fanapt <sup>®</sup> royalty revenue	1,584	2,031	6,502	7,090
Fanapt <sup>®</sup> licensing agreement	7,765	6,752	30,746	26,789
Total revenues	15,370	8,783	50,157	33,879
Operating expenses:				
Cost of sales	682	-	1,583	-
Research and development	4,752	6,270	19,230	28,502
Selling, general and administrative	17,323	9,927	84,644	25,082
Intangible asset amortization	536	377	2,254	1,495
Gain on arbitration settlement	(77,616)	-	(77,616)	-
Total operating expenses	(54,323)	16,574	30,095	55,079
Income (loss) from operations	69,693	(7,791)	20,062	(21,200)
Other income	26	44	124	145
Net income (loss)	\$ 69,719	\$ (7,747)	\$ 20,186	\$ (21,055)

Net income (loss) per share:				
Basic	\$	1.85	\$ (0.23)	\$ 0.58 (0.69)
Diluted	\$	1.77	\$ (0.23)	\$ 0.55 (0.69)
Weighted average shares outstanding:				
Basic		37,622,884	33,283,705	34,774,163 30,351,353
Diluted		39,421,014	33,283,705	36,686,723 30,351,353

**VANDA PHARMACEUTICALS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	December 31, December 31,	
	2014	2013 <sup>(1)</sup>
(\$ in thousands)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 60,901	\$ 64,764
Marketable securities	68,921	65,586
Accounts receivable	3,654	2,031
Inventory	5,170	-
Prepaid expenses and other current assets	3,084	2,703
Restricted cash	-	530
Total current assets	141,730	135,614
Property and equipment, net	2,437	2,198
Intangible assets, net	26,724	5,037
Restricted cash, non-current	785	500
Other assets, non-current	28	-
Total assets	<u>\$ 171,704</u>	<u>\$ 143,349</u>

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:		
Accounts payable	\$ 835	\$ 661
Accrued liabilities	6,502	5,180
Deferred rent	247	221
Deferred revenues	174	26,789
Other liabilities	28	-
Total current liabilities	7,786	32,851
Deferred rent, non-current	3,101	2,888
Deferred revenues, non-current	-	63,486
Total liabilities	10,887	99,225
Stockholders' equity:		
Common stock	41	33
Additional paid-in capital	448,744	352,240
Accumulated other comprehensive income	16	21
Accumulated deficit	(287,984)	(308,170)
Total stockholders' equity	160,817	44,124
Total liabilities and stockholders' equity	<u>\$ 171,704</u>	<u>\$ 143,349</u>

**Reconciliation of GAAP to Non-GAAP Financial Information**

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

	Three Months Ended		Twelve Months Ended	
	December 31,	December 31,	December 31,	December 31,
	2014	2013 <sup>(1)</sup>	2014	2013 <sup>(1)</sup>
(\$ in thousands, except per share amounts)				
Net income (loss)	\$ 69,719	\$ (7,747)	\$ 20,186	\$ (21,055)
Adjustments:				
Fanapt <sup>®</sup> licensing agreement	(7,765)	(6,752)	(30,746)	(26,789)

Stock based compensation	1,631	1,409	5,878	5,404
Intangible asset amortization	536	377	2,254	1,495
Gain on arbitration settlement	(77,616)	-	(77,616)	-
Non-GAAP Net loss	<u>\$ (13,495)</u>	<u>\$ (12,713)</u>	<u>\$ (80,044)</u>	<u>\$ (40,945)</u>
Non-GAAP Net loss per share:				
Basic & diluted	\$ (0.36)	\$ (0.38)	\$ (2.30)	(1.35)
Weighted average shares outstanding:				
Basic & diluted	37,622,884	33,283,705	34,774,163	30,351,353
Total revenues:	\$ 15,370	\$ 8,783	\$ 50,157	33,879
Adjustments:				
Fanapt® licensing agreement	(7,765)	(6,752)	(30,746)	(26,789)
Non-GAAP Total revenues	<u>\$ 7,605</u>	<u>\$ 2,031</u>	<u>\$ 19,411</u>	<u>\$ 7,090</u>
Operating expenses:	\$ (54,323)	16,574	30,095	55,079
Adjustments:				
Cost of sales	(682)	-	(1,583)	-
Stock based compensation	(1,631)	(1,409)	(5,878)	(5,404)
Intangible asset amortization	(536)	(377)	(2,254)	(1,495)
Gain on arbitration settlement	77,616	-	77,616	-
Non-GAAP Operating expenses, excluding Cost of sales	<u>\$ 20,444</u>	<u>\$ 14,788</u>	<u>\$ 97,996</u>	<u>\$ 48,180</u>
Research and development:	\$ 4,752	6,270	19,230	28,502
Adjustments:				
Stock based compensation	(556)	(646)	(1,933)	(2,166)
Non-GAAP Research and development	<u>\$ 4,196</u>	<u>\$ 5,624</u>	<u>\$ 17,297</u>	<u>\$ 26,336</u>
Selling, general and administrative:	\$ 17,323	9,927	84,644	25,082
Adjustments:				
Stock based compensation	(1,075)	(763)	(3,945)	(3,238)
Non-GAAP Selling, general and administrative	<u>\$ 16,248</u>	<u>\$ 9,164</u>	<u>\$ 80,699</u>	<u>\$ 21,844</u>

(1) Prior year amounts have been restated to reflect a change in accounting method for the attribution of stock-based compensation. Refer to the notes to the consolidated financial statements included in the annual report on Form 10-K for the year ending December 31, 2014 to be filed with the SEC.

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