

Vanda Pharmaceuticals Reports First Quarter 2018 Financial Results

May 2, 2018

- Total net product sales were \$43.6 million in the first quarter of 2018
- Vanda reiterates 2018 net product sales guidance of \$180 million to \$200 million

WASHINGTON, May 2, 2018 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: <u>VNDA</u>) today announced financial and operational results for the first guarter ended March 31, 2018.

"We are pleased with the progress made in 2018 with the continued growth of our HETLIOZ business and the successful defense of our U.S. Fanapt franchise," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "Our research and development programs are progressing including life cycle management of commercialized products and the advancement of our late stage clinical pipeline."

Key Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were \$43.6 million during the first quarter of 2018, a 2% decrease compared to \$44.3 million in the fourth quarter of 2017 and a 17% increase compared to \$37.4 million in the first quarter of 2017.
- In March 2018, Vanda completed a public offering of its common stock that resulted in net proceeds of \$100.9 million.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales were \$25.4 million in the first quarter of 2018, a 2% increase compared to \$25.0 million in the fourth guarter of 2017 and a 26% increase compared to \$20.2 million in the first guarter of 2017.
- In April 2018, Vanda filed a lawsuit against Teva Pharmaceuticals USA, Inc. for infringement of HETLIOZ® patents by submitting to the U.S. Food and Drug Administration (the FDA) an Abbreviated New Drug Application for a generic version of HETLIOZ® prior to the expiration of the latest to expire of Vanda's HELTIOZ® patents in 2034.

Fanapt® (iloperidone)

- Fanapt[®] net product sales were \$18.2 million in the first quarter of 2018, a 6% decrease compared to \$19.3 million in the fourth guarter of 2017 and a 5% increase compared to \$17.2 million in the first guarter of 2017.
- Fanapt[®] prescriptions, as reported by IQVIA, were 27,372 in the first quarter of 2018, a 3% decrease compared to the fourth quarter of 2017.
- In April 2018, the U.S. Court of Appeals for the Federal Circuit affirmed the U.S. District Court for the District of Delaware's decision that West Ward Pharmaceuticals, a subsidiary of Hikma Pharmaceuticals, infringed Vanda's U.S. Patent number 8,586,610 (the '610 Patent) for Fanapt[®]. The '610 Patent is set to expire November 2, 2027.

Research and Development

Tradipitant

- Vanda held an end of Phase II meeting with the FDA in April 2018 to discuss the clinical and regulatory path forward for tradipitant as a treatment for chronic pruritus in atopic dermatitis. A Phase III clinical study is expected to begin in the second guarter of 2018.
- A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected by the end of 2018.

HETLIOZ®

- Results from the JET8 Phase III clinical study to treat jet lag disorder in an 8 hour phase advance (3107) showed significant and clinically meaningful effects of HETLIOZ® 20mg on the primary endpoint of the study as well as multiple secondary endpoints in the treatment of jet lag disorder. Vanda intends to seek U.S. marketing approval for the use of HETLIOZ® in the treatment of jet lag disorder.
- A pharmacokinetic study of the HETLIOZ® pediatric liquid formulation is now complete.
- Enrollment in the Smith-Magenis Syndrome clinical study is ongoing. Results are expected by the end of 2018.

VTR-297 (histone deacetylase (HDAC) inhibitor)

• A VTR-297 Phase I study (1101) in patients with hematologic malignancies is expected to start in the second half of 2018.

Cash, cash equivalents and marketable securities (Cash) were \$248.8 million as of March 31, 2018, representing an increase to Cash of \$105.4

million during the first quarter of 2018.

Non-GAAP Financial Results

Non-GAAP net income was \$6.6 million for the first quarter of 2018, or \$0.14 per share, compared to a Non-GAAP net loss of \$4.9 million, or \$0.11 per share, for the first quarter of 2017.

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" for more detailed information regarding Non-GAAP financial information.

2018 Financial Guidance

Vanda reiterates its prior 2018 financial guidance, updates its year-end 2018 Cash⁽¹⁾ guidance, and expects to achieve the following financial objectives in 2018:

Full Year 2018 Financial Objectives	Full Year 2018 Guidance
Combined net product sales from both HETLIOZ® and Fanapt®	\$180 to \$200 million
HETLIOZ® net product sales	\$108 to \$118 million
Fanapt [®] net product sales	\$72 to \$82 million
Non-GAAP Operating expenses, excluding Cost of goods sold ⁽²⁾	\$163 to \$173 million
Intangible asset amortization	\$1.7 million
Stock-based compensation	\$11 to \$15 million
Year-end 2018 Cash ⁽¹⁾	\$215 to \$225 million as compared to prior guidance of \$115 to \$125 million

⁽¹⁾ Year-end 2018 Cash includes the expected payment of a \$25 million milestone obligation based on cumulative HETLIOZ® net product sales and the net proceeds of \$100.9 million from the March 2018 public offering.

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

Conference Call

Vanda has scheduled a conference call for today, Wednesday, May 2, 2018, at 4:30 PM ET. During the call, Vanda's management will discuss the first quarter 2018 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 46823596. A replay of the call will be available on Wednesday, May 2, 2018, beginning at 7:00 PM ET and will be accessible until Wednesday, May 9, 2018, 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 46823596.

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 2018 Non-GAAP Operating expenses, excluding Cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2018 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 global biopharmaceutical company focused on the development and commercialization of innovative 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 under "2018 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. through the HETLIOZ® to Psychiatrists Initiative, among other means, Vanda's ability to complete the clinical development and obtain regulatory approval of tradipitant for the treatment of chronic pruritus in atopic dermatitis, 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, 2017, 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, 2018, to be filed with the SEC in the second quarter of 2018. 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 (in thousands, except for share and per share amounts) (unaudited)

	Three Months Ended		
	Ma	March 31	
		2018	2017
Revenues:			
HETLIOZ [®] product sales, net	\$	25,423	20,182
Fanapt [®] product sales, net		18,169	17,233
Total revenues		43,592	37,415
Operating expenses:			
Cost of goods sold excluding amortization		4,560	4,003
Research and development		9,416	10,567
Selling, general and administrative		26,822	30,297
Intangible asset amortization		352	454
Total operating expenses		41,150	45,321
Income (loss) from operations		2,442	(7,906)
Other income		622	280
Income (loss) before income taxes		3,064	(7,626)
Provision (benefit) for income taxes		(2)	19
Net income (loss)	\$	3,0669	(7,645)
Net income (loss) per share, basic	\$	0.079	(0.17)
Net income (loss) per share, diluted	\$	0.069	(0.17)
Weighted average shares outstanding, basic Weighted average shares outstanding, diluted			44,398,359 44,398,359

(in thousands) (unaudited)

	March 31 2018 ⁽¹⁾		December 31 2017 ⁽¹⁾
ASSETS			
Current assets:			
Cash and cash equivalents	\$	155,293 \$	33,627
Marketable securities		93,541	109,786
Accounts receivable, net		23,314	17,601
Inventory		1,011	840
Prepaid expenses and other current assets		9,276	8,003
Total current assets		282,435	169,857
Property and equipment, net		5,105	5,306
Intangible assets, net		25,717	26,069
Non-current inventory and other		4,058	4,193
Total assets	\$	317,315 \$	205,425
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:			
Accounts payable and accrued liabilities	\$	17,242 \$	20,335
Product revenue allowances		27,713	23,028
Milestone obligations under license agreements		27,000	27,000
Total current liabilities		71,955	70,363
Other non-current liabilities		4,216	3,675
Total liabilities		76,171	74,038
Stockholders' equity:			
Common stock		52	45
Additional paid-in capital		599,480	492,802
Accumulated other comprehensive loss		(28)	(34)
Accumulated deficit		(358,360)	(361,426)
Total stockholders' equity		241,144	131,387
Total liabilities and stockholders' equity	\$	317,315 \$	205,425

⁽¹⁾With the adoption of Accounting Standards Codification Subtopic 606 Revenue from Contracts with Customers on January 1, 2018, provision for product returns is included in product revenue allowances and other non-current liabilities in the current year. Provision for product returns is included in accounts receivable, net in the prior year. Refer to footnote 2 in the quarterly report on Form 10Q for the quarter ending March 31, 2018.

VANDA PHARMACEUTICALS INC. Reconciliation of GAAP to Non-GAAP Financial Information (in thousands, except for share and per share amounts) (unaudited)

	Three Months Ended		
	М	arch 31 2018	March 31 2017
Net income (loss) Adjustments:	\$	3,066\$	
Stock-based compensation		3,151	2,256
Intangible asset amortization Non-GAAP Net income (loss)	\$	352 6,569\$	454 3 (4,935)
Non-GAAP Net income (loss) per share, basic Non-GAAP Net income (loss) per share, diluted		0.14\$ 0.14\$	(-)
Weighted average shares outstanding, basic Weighted average shares outstanding, diluted			44,398,359 44,398,359
Operating expenses Adjustments:	\$	41,150\$	45,321
Cost of goods sold excluding amortization Stock-based compensation Intangible asset amortization		(4,560) (3,151) (352)	(4,003) (2,256) (454)

Non-GAAP Operating expenses excluding Cost of goods sold	\$ 33,087\$	38,608
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Research and development Adjustment:	\$ 9,416\$	10,567
Stock-based compensation	(321)	(409)
Non-GAAP Research and development	\$ 9,095\$	10,158
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Selling, general and administrative	\$ 26,822\$	30,297
Adjustment:		
Stock-based compensation	 (2,830)	(1,847)
Non-GAAP Selling, general and administrative	\$ 23,992\$	28,450
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COMPANY CONTACT:

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

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