Vanda Pharmaceuticals Reports Third Quarter 2017 Financial Results

November 7, 2017

-- Total net product sales were $41.3 million in the third quarter of 2017
-- HETLIOZ® to psychiatrists initiative fully launched in October 2017
-- Tradipitant study showed significant improvement to itch and disease severity in atopic dermatitis
-- Vanda is providing an update to its 2017 Financial Guidance

WASHINGTON, Nov. 7, 2017 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced financial and operational results for the third quarter ended September 30, 2017.

"During the third quarter of 2017, Vanda demonstrated the importance of the diverse set of ongoing initiatives to advance our growth strategy," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "The tradipitant results in atopic dermatitis, early trends from the HETLIOZ to psychiatrists initiative and the resolution of the HETLIOZ pricing negotiation in Germany, all represent significant potential drivers of growth."

Key Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were $41.3 million in the third quarter of 2017, a 2% decrease compared to $42.1 million in the second quarter of 2017 and a 7% increase compared to $38.5 million in the third quarter of 2016.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales were $22.3 million in the third quarter of 2017, a 1% decrease compared to $22.5 million in the second quarter of 2017 and a 19% increase compared to $18.7 million in the third quarter of 2016.
- As of October 2017, the full Fanapt® U.S. field force is promoting HETLIOZ® to psychiatrists for their patients with Non-24-Hour Sleep-Wake Disorder. Early results are encouraging and Vanda believes this initiative has the potential to increase the HETLIOZ® rate of growth in 2018.
- In October 2017, Vanda reached a pricing agreement for HETLIOZ® with the German National Association of Statutory Health Insurance Funds after an Arbitration Board decision. Vanda plans to submit pricing and reimbursement dossiers for HETLIOZ® in both France and Italy in the first half of 2018.

Fanapt® (iloperidone)

- Fanapt® net product sales were $19.1 million in the third quarter of 2017, a 3% decrease compared to $19.5 million in the second quarter of 2017 and a 4% decrease compared to $19.8 million in the third quarter of 2016.
- Fanapt® prescriptions, as reported by QuintilesIMS Incorporated, were 27,797 in the third quarter of 2017, a 2% decline compared to the second quarter of 2017.
- The Federal Circuit Court of Appeals has scheduled oral arguments on December 5, 2017 for the appeal by West-Ward Pharmaceutical's (West-Ward) of the Delaware District Court's decision that West-Ward's ANDA product infringes Vanda's U.S. Patent No. 8,586,610 (the '610 Patent). The Delaware District Court issued an injunction barring West-Ward from marketing its product until the expiration of the '610 Patent on November 2, 2027.

Research and Development

Tradipitant

- In September 2017, results were announced from a Phase II clinical study of tradipitant for patients with atopic dermatitis, which showed significant improvements in itch and disease severity. These results were presented at the 9th World Congress of Itch in October 2017.
- Vanda expects to hold an end of Phase II meeting with the U.S. Food and Drug Administration (FDA) in the first quarter of 2018 to discuss the tradipitant for atopic dermatitis clinical study. A tradipitant for atopic dermatitis Phase III clinical study is expected to begin in the first half of 2018.
- A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected in mid 2018.

HETLIOZ®

- Results from the study of HETLIOZ® for the treatment of jet lag disorder after transmeridian travel (2102) are expected in the fourth quarter of 2017.
- An 8-hour phase advance, simulated jet lag disorder study (3107) was initiated in October 2017 and is expected to be fully

enrolled by the end of 2017. Results are expected in the first quarter of 2018.
- A pharmacokinetic study of the HETLIOZ® pediatric formulation is near completion. The study is expected to be fully enrolled by the end of 2017.
- Enrollment in the Smith-Magenis Syndrome clinical study is ongoing. Results are expected in 2018.

VTR-297 (histone deactetylase (HDAC) inhibitor)

- The FDA has accepted an Investigational New Drug application for VTR-297, a small molecule HDAC inhibitor, and has provided authorization to proceed with the treatment of patients with relapsed and/or refractory hematologic malignancies.
- A VTR-297 Phase I study (1101) is expected to start in the first half of 2018. The 1101 study is a dose escalation trial to evaluate drug safety, tolerability and determine a recommended clinical treatment regimen and dose.

Cash, cash equivalents and marketable securities (Cash) were $139.9 million as of September 30, 2017, representing an increase to Cash of $2.8 million during the third quarter of 2017.

Non-GAAP Financial Results

For the third quarter of 2017, Non-GAAP net loss was $1.3 million, or $0.03 per share, compared to a Non-GAAP net income of $4.6 million, or $0.11 per share, for the third quarter of 2016.

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."

2017 Financial Guidance

Vanda is updating its 2017 financial guidance and expects to achieve the following financial objectives in 2017:

Fourth Quarter 2017 Financial Objectives	Fourth Quarter 2017 Guidance
Combined net product sales from both HETLIOZ® and Fanapt®	$42 to $48 million
HETLIOZ® net product sales	$24 to $27 million
Fanapt® net product sales	$18 to $21 million

Full Year 2017 Financial Objectives	Revised Full Year 2017 Guidance	Prior Full Year 2017 Guidance
Combined net product sales from both HETLIOZ® and Fanapt®	$163 to $169 million	$165 to $175 million
HETLIOZ® net product sales	$89 to $92 million	$88 to $93 million
Fanapt® net product sales	$74 to $77 million	$77 to $82 million
Non-GAAP Operating expenses, excluding Cost of goods sold[(1)]	$150 to $157 million	$162 to $172 million
Intangible asset amortization	$1.7 million	$1.7 million
Stock-based compensation	$9 to $12 million	$9 to $12 million
Year-end 2017 Cash	$131 to $141 million	$121 to $141 million

[(1)] 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, Tuesday, November 7, 2017, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 2017 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 45886211. A replay of the call will be available on Tuesday, November 7, 2017, beginning at 7:00 PM ET and will be accessible until Tuesday, November 14, 2017, 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 45886211.

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 2017 Non-GAAP Operating expenses, excluding Cost of goods sold, a forward-looking Non-GAAP financial measure under the heading "2017 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 "2017 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 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, 2016 and quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2017, 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 quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2017, to be filed with the SEC in the fourth quarter of 2017. 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		Nine Months Ended	
	September 30 2017	September 30 2016	September 30 2017	September 30 2016
Revenues:				
HETLIOZ®product sales, net	$ 22,279	$ 18,715	$ 64,968	$ 52,376
Fanapt®product sales, net	19,057	19,767	55,839	55,397
Total revenues	41,336	38,482	120,807	107,773
Operating expenses:				
Cost of goods sold excluding amortization	4,525	6,990	13,057	19,440
Research and development	10,178	7,294	28,393	21,542
Selling, general and administrative	31,124	21,908	92,792	75,880
Intangible asset amortization	432	2,943	1,318	8,828
Total operating expenses	46,259	39,135	135,560	125,690
Loss from operations	(4,923)	(653)	(14,753)	(17,917)
Other income	396	223	1,073	511
Loss before income taxes	(4,527)	(430)	(13,680)	(17,406)
Provision for income taxes	23	-	49	-

Net loss	$ (4,550)	$ (430)	$ (13,729)	$ (17,406)
Net loss per share, basic and diluted	$ (0.10)	$ (0.01)	$ (0.31)	$ (0.40)
Weighted average shares outstanding, basic and diluted	44,885,287	43,515,404	44,669,201	43,275,074

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30 2017	December 31 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,586	$ 40,426
Marketable securities	117,295	100,914
Accounts receivable, net	18,179	20,268
Inventory	921	779
Prepaid expenses and other current assets	10,738	11,788
Total current assets	169,719	174,175
Property and equipment, net	5,448	5,015
Intangible assets, net	26,501	27,819
Non-current inventory and other	4,038	3,365
Total assets	$ 205,706	$ 210,374
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 18,921	$ 16,196
Accrued government and other rebates	25,615	34,124
Milestone obligations under license agreements	27,000	-
Total current liabilities	71,536	50,320
Milestone obligation under license agreement	-	25,000
Other non-current liabilities	3,701	3,724
Total liabilities	75,237	79,044
Stockholders' equity:		
Common stock	45	44
Additional paid-in capital	489,939	477,087
Accumulated other comprehensive income	73	58
Accumulated deficit	(359,588)	(345,859)
Total stockholders' equity	130,469	131,330
Total liabilities and stockholders' equity	$ 205,706	$ 210,374

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

	Three Months Ended		Nine Months Ended	
	September 30 2017	September 30 2016	September 30 2017	September 30 2016
Net loss	$ (4,550)	$ (430)	$ (13,729)	$ (17,406)
Adjustments:				
Stock-based compensation	2,771	2,100	7,683	6,440
Intangible asset amortization	432	2,943	1,318	8,828
Non-GAAP Net income (loss)	$ (1,347)	$ 4,613	$ (4,728)	$ (2,138)
Non-GAAP Net income (loss) per share, basic	$ (0.03)	$ 0.11	$ (0.11)	$ (0.05)
Weighted average shares outstanding, basic	44,885,287	43,515,404	44,669,201	43,275,074
Operating expenses	$ 46,259	$ 39,135	$ 135,560	$ 125,690
Adjustments:				

Cost of goods sold excluding amortization	(4,525)	(6,990)	(13,057)	(19,440)
Stock-based compensation	(2,771)	(2,100)	(7,683)	(6,440)
Intangible asset amortization	(432)	(2,943)	(1,318)	(8,828)
Non-GAAP Operating expenses excluding Cost of goods sold	$ 38,531	$ 27,102	$ 113,502	$ 90,982
Research and development	$ 10,178	$ 7,294	$ 28,393	$ 21,542
Adjustment:				
Stock-based compensation	(264)	(539)	(958)	(1,552)
Non-GAAP Research and development	$ 9,914	$ 6,755	$ 27,435	$ 19,990
Selling, general and administrative	$ 31,124	$ 21,908	$ 92,792	$ 75,880
Adjustment:				
Stock-based compensation	(2,507)	(1,561)	(6,725)	(4,888)
Non-GAAP Selling, general and administrative	$ 28,617	$ 20,347	$ 86,067	$ 70,992

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