

Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results

February 25, 2020

- Full year 2019 total revenues grew to \$227.2 million, an 18% increase compared to 2018
 - Full year 2020 total revenues expected to be between \$240 million and \$260 million
- Results from the EPIONE study of Tradipitant in the treatment of Pruritus in Atopic Dermatitis reported today

WASHINGTON, Feb. 25, 2020 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the fourth quarter and full year ended December 31, 2019.

"We had another year of outstanding commercial growth," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "I have never been more excited about the opportunities ahead with our relentless focus on developing innovative therapies for patients in need."

Key Financial Highlights

- Total revenues were \$60.9 million in the fourth quarter of 2019, a 15% increase compared to \$53.0 million in the fourth quarter of 2018. Total revenues were \$227.2 million for the full year 2019, an 18% increase compared \$193.1 million for the full year 2018.
- HETLIOZ® net product sales were \$38.6 million in the fourth quarter of 2019, a 19% increase compared to \$32.4 million in the fourth quarter of 2018. HETLIOZ® net product sales were \$143.0 million for the full year 2019, a 23% increase compared to \$115.8 million for the full year 2018.
- Fanapt[®] net product sales were \$22.3 million in the fourth quarter of 2019, an 8% increase compared to \$20.6 million in the fourth quarter of 2018. Fanapt[®] net product sales were \$84.2 million for the full year 2019, a 9% increase compared to \$77.3 million for the full year 2018.
- Cash, cash equivalents and marketable securities (Cash) were \$312.1 million as of December 31, 2019, representing an increase to Cash of \$54.8 million compared to December 31, 2018.

Key Product and Pipeline Highlights

Tradipitant

- Results from the EPIONE study of tradipitant in the treatment of pruritus in atopic dermatitis were reported today. Vanda will reassess EPIONE 2 and determine next steps.
- Enrollment in the Phase III study of tradipitant in gastroparesis (VP-VLY-686-3301) is ongoing.
- Vanda expects to complete the Phase III program of tradipitant in motion sickness and file a New Drug Application with the U.S. Food and Drug Administration (FDA) in 2020.
- Vanda continues to engage with the FDA over the requirement of a 9-month dog toxicity study.

HETLIOZ® (tasimelteon)

- Vanda submitted a supplemental New Drug Application (sNDA) for HETLIOZ® in Smith-Magenis Syndrome (SMS), including data for a liquid formulation, and expects regulatory action by the FDA in 2020.
- Vanda continues to pursue approval for HETLIOZ[®] in the treatment of jet lag disorder (JLD).
- A clinical program for HETLIOZ® in delayed sleep phase disorder (DSPD) is ongoing.

Fanapt® (iloperidone)

- A Phase III study of Fanapt® in bipolar disorder is ongoing.
- Development of the long acting injectable (LAI) formulation of Fanapt[®] is ongoing.

GAAP Financial Results

Net income was \$4.2 million for the fourth quarter of 2019, compared to net income of \$10.4 million for the fourth quarter of 2018. Diluted net income per share was \$0.08 in the fourth quarter of 2019, compared to \$0.19 in the fourth quarter of 2018.

Net income was \$115.6 million for the full year 2019, compared to net income of \$25.2 million, for the full year 2018. Diluted net income per share was \$2.11 for the full year 2019, compared to \$0.48 for the full year 2018. The income tax benefit of \$86.5 million reflected in the financial results for the full year 2019 includes the favorable impact of the release of Vanda's deferred tax asset valuation allowance.

2020 Financial Guidance

Vanda expects to achieve the following financial objectives in 2020:

Full Year 2020 Financial Objectives	Full Year 2020 Guidance
Total revenues	\$240 to \$260 million
HETLIOZ [®] net product sales	\$155 to \$165 million
Fanapt [®] net product sales	\$85 to \$95 million
Year-end 2020 Cash	Greater than \$320 million

Conference Call

Vanda has scheduled a conference call for today, Tuesday, February 25, 2020, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2019 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 2149683. A replay of the call will be available on Tuesday, February 25, 2020, beginning at 7:30 PM ET and will be accessible until Tuesday, March 3, 2020, at 7:30 PM ET. The replay call-in number is 1-855-859-2056 for domestic callers and 1-404-537-3406 for international callers. The passcode number is 2149683.

The conference call will be broadcast simultaneously on Vanda's website, www.vandapharma.com. Investors should click on the Investors 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.

About Vanda Pharmaceuticals Inc.

Vanda is a leading 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 "2020 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 complete the clinical development and obtain regulatory approval for tradipitant in the treatment of motion sickness, gastroparesis and/or atopic dermatitis, Vanda's discussion and potential resolution of the deficiencies that the FDA believes are contained in the sNDA for HETLIOZ® for the treatment of JLD and Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of JLD following any such resolution. Vanda's ability to complete the clinical development, submit an sNDA and obtain regulatory approval for tasimelteon in the treatment of sleep disorders in patients with SMS, Vanda's ability to complete the clinical development and obtain regulatory approval for Fanapt® in bipolar disorder and Fanapt® LAI in schizophrenia, 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, 2018 and quarterly report on Form 10-Q for the quarter ended September 30, 2019, 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 year ended December 31, 2019, to be filed with the SEC in the first quarter of 2020. 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		Twelve Months Ended		
	December 31December 31December 31				
		2019	2018	2019	2018
Revenues:					
HETLIOZ [®] product sales, net	\$	38,599\$	32,444\$	142,980\$	115,835
Fanapt [®] product sales, net		22,331	20,597	84,208	77,283
Total revenues		60,930	53,041	227,188	193,118
Operating expenses:					
Cost of goods sold excluding amortization		6,225	5,667	24,488	20,508
Research and development		13,074	12,922	48,649	43,594
Selling, general and administrative		37,018	24,922	129,736	105,751

Intangible asset amortization	370	380	1,505	1,527
Total operating expenses	56,687	43,891	204,378	171,380
Income from operations	4,243	9,150	22,810	21,738
Other income	1,567	1,168	6,218	3,608
Income before income taxes	5,810	10,318	29,028	25,346
Provision (benefit) for income taxes	1,594	(42)	(86,525)	138
Net income	\$ 4,216\$	10,360\$	115,553\$	25,208
Net income per share, basic	\$ 0.08\$	0.20\$	2.17\$	0.50
Net income per share, diluted	\$ 0.08\$	0.19\$	2.11\$	0.48
Weighted average shares outstanding, basic	53,389,950	52,457,275	53,137,562	50,859,947
Weighted average shares outstanding, basic Weighted average shares outstanding, dilute	54,973,952	55,216,507	54,847,060	53,045,257

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

	ember 31 019 (1)	December 31 2018 (1)	
ASSETS	 . ,	. ,	
Current assets:			
Cash and cash equivalents	\$ 45,072 \$	61,005	
Marketable securities	267,057	196,355	
Accounts receivable, net	26,367	28,780	
Inventory	1,140	994	
Prepaid expenses and other current assets	 14,500	11,998	
Total current assets	354,136	299,132	
Property and equipment, net	3,864	4,417	
Operating lease right-of-use assets	11,180	-	
Intangible assets, net	23,037	24,542	
Deferred tax assets	87,680	-	
Non-current inventory and other	 3,851	4,039	
Total assets	\$ 483,748 \$	332,130	
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable and accrued liabilities	\$ 27,590 \$	21,584	
Product revenue allowances	31,915	31,231	
Milestone obligations under license agreements Total current liabilities	 59,505	200 53,015	
Operating loads pen augrent lightlities	10.455		
Operating lease non-current liabilities	12,455 843	3,693	
Other non-current liabilities Total liabilities	 72,803	56,708	
Stockholders' equity:			
Common stock	54	52	
Additional paid-in capital	631,307	611,587	
Accumulated other comprehensive income	249	1	
Accumulated deficit	(220,665)	(336,218)	
Total stockholders' equity	 410,945	275,422	
Total liabilities and stockholders' equity	\$ 483,748 \$	332,130	

⁽¹⁾With the adoption of Accounting Standards Codification Subtopic ASC 842, Leases, on January 1, 2019, Vanda recognized operating lease liabilities and right-of-use assets. Prior period financial statements were not recast for the new leasing standard. For more information, please refer to footnote 2 in the annual report on Form 10-K for the year ended December 31, 2019, to be filed in the first quarter of 2020.

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