Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results

February 8, 2023

- *Q4 2022 total revenues were $64.5 million*
- *Full year 2022 revenues were $254.4 million*
- *Vanda provides update on pipeline advancements and upcoming milestones*

WASHINGTON, Feb. 8, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the fourth quarter and full year ended December 31, 2022.

"Our strong full year 2022 commercial performance positions Vanda well towards our objectives as we pursue a number of near term regulatory filings in bipolar I disorder, gastroparesis and insomnia," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "At the same time, we continue to believe in the strength of our intellectual property portfolio as we proceed with our appeal in the HETLIOZ patent litigation."

Financial Highlights

Fourth Quarter of 2022

- Total net product sales from HETLIOZ® and Fanapt® were $64.5 million in the fourth quarter of 2022, a 5% decrease compared to $68.0 million in the fourth quarter of 2021.
- HETLIOZ® net product sales were $40.1 million in the fourth quarter of 2022, a 9% decrease compared to $44.1 million in the fourth quarter of 2021, due in part to continued reimbursement challenges for prescriptions for patients with Non-24-Hour Sleep-Wake Disorder (Non-24).
- Fanapt® net product sales were $24.4 million in the fourth quarter of 2022, a 2% increase compared to $24.0 million in the fourth quarter of 2021.
- Net income was $6.9 million in the fourth quarter of 2022 compared to $7.1 million in the fourth quarter of 2021.
- Cash, cash equivalents and marketable securities (Cash) was $466.9 million as of December 31, 2022, representing an increase to Cash of $12.1 million, or 3%, compared to September 30, 2022.

Full Year 2022

- Total net product sales from HETLIOZ® and Fanapt® were $254.4 million for the full year 2022, a 5% decrease compared to $268.7 million for the full year 2021.
- HETLIOZ® net product sales were $159.7 million for the full year 2022, an 8% decrease compared to $173.5 million for the full year 2021, due in part to continued reimbursement challenges for prescriptions for patients with Non-24.
- Fanapt® net product sales were $94.7 million for the full year 2022, essentially flat compared to $95.1 million for the full year 2021.
- Net income was $6.3 million for the full year 2022 compared to net income of $33.2 million for the full year 2021.
- Cash, cash equivalents and marketable securities (Cash) was $466.9 million as of December 31, 2022, representing an increase to Cash of $34.0 million, or 8%, compared to December 31, 2021.

Key Operational Highlights

HETLIOZ® (tasimelteon)

- Vanda is continuing to pursue regulatory approvals for HETLIOZ® in the indications of insomnia and jet lag disorder.
- In December 2022, the U.S. District Court for the District of Delaware delivered its decision for the consolidated HETLIOZ® patent lawsuit against defendants Teva Pharmaceuticals USA, Inc. (Teva) and Apotex Inc. and Apotex Corp. (Apotex), ruling in favor of the defendants. Vanda filed an appeal to the U.S. Court of Appeals for the Federal Circuit where an oral argument is scheduled for March 14, 2023. Despite the pending appeal, Teva has launched at risk its generic version of HETLIOZ® in the U.S.
- In December 2022, Vanda filed patent infringement lawsuits against each of Teva and Apotex in the U.S. District Court for the District of New Jersey asserting that Teva and Apotex's generic versions of HETLIOZ® infringe U.S. Patent No. 11,285,129.

Tradipitant

- Vanda is continuing to conduct an open-label safety study for tradipitant in gastroparesis and approximately the first 400 patients enrolled in the study were locked in preparation for the Company's planned New Drug Application (NDA) submission. The study continues to enroll open label patients and Vanda continues to receive requests from patients

seeking access to tradipitant through the Expanded Access program, which has multiple patients who have taken tradipitant for more than one year.
- Vanda is preparing for the submission of an NDA for tradipitant for patients with gastroparesis. Vanda expects to submit this NDA to the FDA in the first half of 2023.
- The Phase III study of tradipitant in the treatment of motion sickness is over 75% enrolled. Results are expected by mid-2023.

Fanapt® (iloperidone)

- In December 2022, Vanda announced positive results in the Phase III clinical study of Fanapt® in acute manic and mixed episodes associated with bipolar I disorder in adults. Vanda plans to submit a supplemental New Drug Application (sNDA) in the first half of 2023.

Early-Stage Programs

- In December 2022, Vanda announced results in a Phase II clinical study of VQW-765 in the treatment of acute performance anxiety in social situations. This is the first time that an alpha 7 nicotinic acetylcholine receptor (α7-nAChR) partial agonist has shown efficacy in a clinical study of performance anxiety.

GAAP Financial Results

Net income was $6.9 million in the fourth quarter of 2022 compared to net income of $7.1 million in the fourth quarter of 2021. Diluted net income per share was $0.12 in the fourth quarter of 2022 compared to diluted net income per share of $0.12 in the fourth quarter of 2021.

Net income was $6.3 million for the full year 2022 compared to net income of $33.2 million for the full year 2021. Diluted net income per share was $0.11 for the full year 2022 compared to diluted net income per share of $0.58 for the full year 2021.

2023 Financial Guidance

Given uncertainties surrounding the U.S. market for HETLIOZ® for the treatment of Non-24 as a result of the ongoing HETLIOZ® patent litigation, Vanda is unable to provide 2023 financial guidance at this time. Vanda will continue to evaluate its ability to provide financial guidance as the year progresses.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, February 8, 2023, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2022 financial results and other corporate activities. Investors can call 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and use passcode number 4734670. A replay of the call will be available on Wednesday, February 8, 2023, beginning at 8:30 PM ET and will be accessible until Wednesday, February 15, 2023 at 8:30 PM ET. The replay call-in number is 1-800-770-2030 for domestic callers and 1-609-800-9909 for international callers. The passcode number is 4734670.

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 and follow us on Twitter @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, statements regarding Vanda's plans for pursuit of regulatory approval of HETLIOZ® in the treatments of insomnia and jet lag disorder, tradipitant in the treatment of patients with gastroparesis and Fanapt® in the treatment of bipolar I in adults and the clinical development timeline for tradipitant in the treatment of motion sickness are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances 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 complete and submit the NDA for tradipitant and the sNDAs for HETLIOZ® and Fanapt® in the specified timeframes, the FDA's assessment of the sufficiency of the data packages to be included in Vanda's planned NDA submission for tradipitant and sNDA submissions for HETLIOZ® and Fanapt®, and Vanda's ability to complete the Phase III clinical study of tradipitant in the treatment of motion sickness by mid-2023. Therefore, no assurance can be given that the 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. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's most recent Annual Report on Form 10-K, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

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 press release is provided only as of the date of this press 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, except as required by law.

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 31 2022	December 31 2021	December 31 2022	December 31 2021
Revenues:				
HETLIOZ® net product sales	$ 40,101	$ 44,069	$ 159,655	$ 173,536
Fanapt® net product sales	24,381	23,950	94,727	95,146
Total revenues	64,482	68,019	254,382	268,682
Operating expenses:				
Cost of goods sold excluding amortization	6,238	6,236	24,282	25,629
Research and development	18,454	19,331	85,770	75,363
Selling, general and administrative	32,782	33,447	136,485	124,047
Intangible asset amortization	379	369	1,516	1,478
Total operating expenses	57,853	59,383	248,053	226,517
Income from operations	6,629	8,636	6,329	42,165
Other income (expense)	2,984	(26)	4,971	199
Income before income taxes	9,613	8,610	11,300	42,364
Provision for income taxes	2,752	1,532	5,025	9,212
Net income	$ 6,861	$ 7,078	$ 6,275	$ 33,152
Net income per share, basic	$ 0.12	$ 0.13	$ 0.11	$ 0.60
Net income per share, diluted	$ 0.12	$ 0.12	$ 0.11	$ 0.58
Weighted average shares outstanding, basic	56,651,984	55,787,252	56,461,877	55,548,122
Weighted average shares outstanding, diluted	57,188,551	57,229,805	56,983,171	56,921,836

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

	December 31 2022	December 31 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,029	$ 52,071
Marketable securities	331,830	380,742
Accounts receivable, net	33,512	32,467
Inventory	1,194	1,025
Prepaid expenses and other current assets	17,727	11,996
Total current assets	519,292	478,301
Property and equipment, net	2,573	3,113
Operating lease right-of-use assets	8,400	9,272
Intangible assets, net	18,565	20,081
Deferred tax assets	74,039	74,878
Non-current inventory and other	11,378	8,147
Total assets	$ 634,247	$ 593,792
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 45,551	$ 34,438
Product revenue allowances	45,885	39,981
Total current liabilities	91,436	74,419
Operating lease non-current liabilities	8,813	10,055
Other non-current liabilities	6,800	4,390
Total liabilities	107,049	88,864
Stockholders' equity:		
Common stock	57	56
Additional paid-in capital	686,235	669,223
Accumulated other comprehensive loss	(1,193)	(175)
Accumulated deficit	(157,901)	(164,176)

Total stockholders' equity	527,198	504,928
Total liabilities and stockholders' equity	$ 634,247	$ 593,792

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