Vanda Pharmaceuticals Reports Third Quarter 2022 Financial Results

November 2, 2022

- *Q3 2022 total revenues were $65.3 million*
- *Total revenues in the first nine months of 2022 were $189.9 million*
- *Vanda provides update on pipeline advancements and upcoming milestones*

WASHINGTON, Nov. 2, 2022 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2022.

"We continue to focus on strong commercial execution, the advancement of our clinical pipeline and our upcoming regulatory milestones of the submissions of an NDA for tradipitant in gastroparesis and an sNDA for HETLIOZ® in insomnia," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "With stable, mature revenue, efficient operations and strong cash on hand, we are well positioned to deliver long-term growth."

Financial Highlights

Third Quarter of 2022

- Total net product sales from HETLIOZ® and Fanapt® were $65.3 million in the third quarter of 2022, a 7% decrease compared to $70.1 million in the third quarter of 2021.
- HETLIOZ® net product sales were $41.3 million in the third quarter of 2022, a 9% decrease compared to $45.6 million in the third quarter of 2021, due in part to continued reimbursement challenges for prescriptions for patients with Non-24.
- Fanapt® net product sales were $24.0 million in the third quarter of 2022, a 2% decrease compared to $24.5 million in the third quarter of 2021.
- Net income was $3.3 million in the third quarter of 2022 compared to $7.8 million in the third quarter of 2021.
- Cash, cash equivalents and marketable securities (Cash) was $454.8 million as of September 30, 2022, representing an increase to Cash of $13.9 million, or 3%, compared to June 30, 2022.

First Nine Months of 2022

- Total net product sales from HETLIOZ® and Fanapt® were $189.9 million in the first nine months of 2022, a 5% decrease compared to $200.7 million in the first nine months of 2021.
- HETLIOZ® net product sales were $119.6 million in the first nine months of 2022, an 8% decrease compared to $129.5 million in the first nine months of 2021, due in part to continued reimbursement challenges for prescriptions for patients with Non-24.
- Fanapt® net product sales were $70.3 million in the first nine months of 2022, a 1% decrease compared to $71.2 million in the first nine months of 2021.
- Net loss was $0.6 million in the first nine months of 2022 compared to net income of $26.1 million in the first nine months of 2021.
- Cash, cash equivalents and marketable securities (Cash) was $454.8 million as of September 30, 2022, representing an increase to Cash of $48.8 million, or 12%, compared to September 30, 2021.

Key Operational Highlights

HETLIOZ® (tasimelteon)

- Vanda is preparing for the submission of a supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of insomnia. Vanda expects to submit this sNDA to the U.S. Food and Drug Administration (FDA) by the end of 2022.

Tradipitant

- Vanda is continuing to conduct an open-label safety study for tradipitant in gastroparesis and continues to receive requests from patients seeking access to tradipitant through the Expanded Access program that has multiple patients who have taken tradipitant for more than a year.
- Vanda is preparing for the submission of a New Drug Application (NDA) for tradipitant in the short-term treatment of nausea in 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 approximately 40% enrolled. Results are expected by mid-2023.

Fanapt® (iloperidone)

- Enrollment of the Phase III clinical study of Fanapt® in acute manic episodes in patients with bipolar I disorder is fully enrolled. The study is a placebo controlled four-week evaluation of approximately 400 patients at sites in the U.S. and Europe. Results are expected by the end of 2022.

Early-Stage Programs

- The Phase II clinical study of a single-dose treatment of VQW-765 to alleviate social/performance anxiety is fully enrolled. Results are expected by the end of 2022.
- In September 2022, Vanda and OliPass Corporation (OliPass) announced a research and development agreement to jointly develop a set of antisense oligonucleotide (ASO) molecules based on OliPass' proprietary modified peptide nucleic acids. Vanda has already identified two ASO targets that have been validated in cell lines that model two disease targets, one rare orphan and the other applicable to a broad set of immuno-oncological conditions.
- In October 2022, Vanda announced that the FDA has granted Orphan Drug Designation for VPO-227 (formerly BPO-27) for the treatment of cholera. Vanda expects to submit an Investigational New Drug (IND) application to the FDA for VPO-227 in 2023.

Legal and Regulatory Updates

- The decision for the consolidated HETLIOZ® patent lawsuit against Abbreviated New Drug Application (ANDA) defendants is expected from the court by the end of 2022.
- Vanda's lawsuit against the Centers for Medicare & Medicaid Services (CMS) is currently pending and challenges a CMS rule that subjects certain of Vanda's products to enhanced rebates. Vanda believes the rule is unlawful and contrary to the intent of Congress when it passed the Affordable Care Act.
- Vanda filed a lawsuit against the FDA on September 13, 2022 demanding that the FDA immediately publish in the Federal Register a notice of opportunity for a hearing on Vanda's sNDA for HETLIOZ® in the treatment of Jet Lag Disorder. The FDA then published the notice in the Federal Register on October 11, 2022. Vanda intends to continue pursuing FDA approval of the sNDA for HETLIOZ® in the treatment of Jet Lag Disorder.

GAAP Financial Results

Net income was $3.3 million in the third quarter of 2022 compared to net income of $7.8 million in the third quarter of 2021. Diluted net income per share was $0.06 in the third quarter of 2022 compared to diluted net income per share of $0.14 in the third quarter of 2021.

Net loss was $0.6 million in the first nine months of 2022 compared to net income of $26.1 million in the first nine months of 2021. Diluted net loss per share was $0.01 in the first nine months of 2022 compared to diluted net income per share of $0.46 in the first nine months of 2021.

2022 Financial Guidance

Vanda is updating its 2022 financial guidance and expects to achieve the following financial objectives in 2022:

Full Year 2022 Financial Objectives	Revised Full Year 2022 Guidance	Prior Full Year 2022 Guidance
Total revenues	$240 to $270 million	$240 to $280 million
HETLIOZ® net product sales	$150 to $170 million	$150 to $180 million
Fanapt® net product sales	$90 to $100 million	$90 to $100 million
Year-end 2022 Cash	Greater than $450 million	Greater than $440 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, November 2, 2022, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 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 5456289. A replay of the call will be available on Wednesday, November 2, 2022, beginning at 8:30 PM ET and will be accessible until Wednesday, November 9, 2022 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 5456289.

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, the guidance provided under "2022 Financial Guidance" above and statements regarding Vanda's plans for pursuit of regulatory approval of HETLIOZ® in the treatment of insomnia and Jet Lag Disorder, and tradipitant in the short-term treatment of nausea in gastroparesis and in the treatment of motion sickness, the research and development activities of the strategic partnership between Vanda and OliPass and the potential therapeutic opportunities that may result from it, Vanda's clinical development and regulatory plans and strategies for VPO-227, the timing of the court's decision with respect to the Company's HETLIOZ® patent litigation, and the clinical development timelines for tradipitant, Fanapt® and VQW-765 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 assumptions regarding the strength of its business in the U.S., Vanda's ability to complete and submit the NDA and sNDA for tradipitant and HETLIOZ®, respectively, in the fourth quarter of 2022 and the first half of 2023, respectively, the FDA's assessment of the sufficiency of the data packages to be included in Vanda's planned NDA and sNDA submissions for tradipitant and HETLIOZ®, respectively, Vanda's ability to complete the Phase III clinical study of tradipitant in the treatment of motion sickness by mid-2023, Vanda's ability to complete the Phase III clinical study of Fanapt® in bipolar I disorder in the fourth quarter of 2022, Vanda's ability to complete the Phase II clinical study of VQW-765 in social/performance anxiety in the fourth quarter of 2022, Vanda's ability to progress the two ASO targets it has identified, and Vanda's ability to complete the IND for VPO-227 and submit it to the FDA in 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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		Nine Months Ended	
	September 30 2022	September 30 2021	September 30 2022	September 30 2021
Revenues:				
HETLIOZ® net product sales	$ 41,335	$ 45,615	$ 119,554	$ 129,467
Fanapt® net product sales	23,983	24,480	70,346	71,196
Total revenues	65,318	70,095	189,900	200,663
Operating expenses:				
Cost of goods sold excluding amortization	6,320	6,797	18,044	19,393
Research and development	24,857	19,653	67,316	56,032
Selling, general and administrative	29,854	32,456	103,703	90,600
Intangible asset amortization	379	370	1,137	1,109
Total operating expenses	61,410	59,276	190,200	167,134
Income (loss) from operations	3,908	10,819	(300)	33,529
Other income (expense)	1,553	(97)	1,987	225
Income before income taxes	5,461	10,722	1,687	33,754
Provision for income taxes	2,191	2,951	2,273	7,680
Net income (loss)	$ 3,270	$ 7,771	$ (586)	$ 26,074
Net income (loss) per share, basic	$ 0.06	$ 0.14	$ (0.01)	$ 0.47
Net income (loss) per share, diluted	$ 0.06	$ 0.14	$ (0.01)	$ 0.46
Weighted average shares outstanding, basic	56,574,503	55,668,156	56,397,805	55,467,528
Weighted average shares outstanding, diluted	56,969,033	57,040,736	56,397,805	56,818,295

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

	September 30 2022	December 31 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 49,397	$ 52,071
Marketable securities	405,394	380,742
Accounts receivable, net	29,352	32,467
Inventory	1,590	1,025
Prepaid expenses and other current assets	21,373	11,996
Total current assets	507,106	478,301
Property and equipment, net	2,594	3,113
Operating lease right-of-use assets	8,262	9,272
Intangible assets, net	18,944	20,081
Deferred tax assets	74,529	74,878
Non-current inventory and other	10,353	8,147
Total assets	$ 621,788	$ 593,792
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 50,125	$ 34,438
Product revenue allowances	42,498	39,981
Total current liabilities	92,623	74,419
Operating lease non-current liabilities	8,903	10,055
Other non-current liabilities	4,605	4,390
Total liabilities	106,131	88,864
Stockholders' equity:		
Common stock	57	56
Additional paid-in capital	681,847	669,223
Accumulated other comprehensive loss	(1,485)	(175)
Accumulated deficit	(164,762)	(164,176)
Total stockholders' equity	515,657	504,928
Total liabilities and stockholders' equity	$ 621,788	$ 593,792

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