Vanda Pharmaceuticals Reports Second Quarter 2022 Financial Results

August 3, 2022

- *Q2 2022 total revenues were $64.4 million*
- *Total revenues in the first six months of 2022 were $124.6 million*
- *Vanda provides update on pipeline advancements and upcoming milestones*

WASHINGTON, Aug. 3, 2022 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2022.

"During the second quarter we made significant progress towards commercializing our products and improving access to HETLIOZ® for patients with Non-24," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "We advanced our clinical pipeline, with significant clinical milestones expected in the coming quarters, and we are preparing our NDA for tradipitant in gastroparesis and our sNDA for HETLIOZ® in insomnia."

Financial Highlights

Second Quarter of 2022

- Total net product sales from HETLIOZ® and Fanapt® were $64.4 million in the second quarter of 2022, a 5% decrease compared to $67.9 million in the second quarter of 2021.
- HETLIOZ® net product sales were $41.2 million in the second quarter of 2022, a 7% decrease compared to $44.5 million in the second quarter of 2021, due in part to continued reimbursement challenges for prescriptions for patients with Non-24.
- Fanapt® net product sales were $23.2 million in the second quarter of 2022, a 1% decrease compared to $23.4 million in the second quarter of 2021.
- Net income was $2.6 million in the second quarter of 2022 compared to $9.7 million in the second quarter of 2021.

First Six Months of 2022

- Total net product sales from HETLIOZ® and Fanapt® were $124.6 million in the first six months of 2022, a 5% decrease compared to $130.6 million in the first six months of 2021.
- HETLIOZ® net product sales were $78.2 million in the first six months of 2022, a 7% decrease compared to $83.9 million in the first six months of 2021, due in part to continued reimbursement challenges for prescriptions for patients with Non-24.
- Fanapt® net product sales were $46.4 million in the first six months of 2022, a 1% decrease compared to $46.7 million in the first six months of 2021.
- Net loss was $3.9 million in the first six months of 2022 compared to net income of $18.3 million in the first six months of 2021.
- Cash, cash equivalents and marketable securities (Cash) was $440.9 million as of June 30, 2022, representing an increase to Cash of $44.4 million compared to June 30, 2021.

Key Operational Highlights

HETLIOZ® (tasimelteon)

- Clinical trials for HETLIOZ® in delayed sleep phase disorder (DSPD) and sleep disturbances in autism spectrum disorder (ASD) are currently enrolling patients.
- Vanda is preparing for the submission of a supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of insomnia.

- Since November 2021, more than 15 states have revised or agreed to revise their Medicaid prior authorization criteria to broaden access to HETLIOZ® for patients with Non-24 and patients with nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

- In July 2022, an Administrative Law Judge struck down a Medicare Part D plan policy that blocked HETLIOZ® coverage for sighted Non-24 patients. Vanda intends to advocate with other Part D plans to challenge similar policies and improve HETLIOZ® access for Non-24 patients.

- In January 2022, Vanda settled its HETLIOZ® patent litigation against one of the Abbreviated New Drug Application (ANDA) defendants. The trial for the consolidated lawsuit against the remaining defendants was held in March 2022. A decision is expected from the court 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 recently held a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) to discuss the planned New Drug Application (NDA) submission for tradipitant in the short-term treatment of nausea in gastroparesis. Vanda is preparing for the submission of the NDA for this indication.

- The Phase III study of tradipitant in the treatment of motion sickness is approximately 30% enrolled.

Fanapt® (iloperidone)

- Enrollment of the Phase III clinical study of Fanapt® in acute manic episodes in patients with bipolar disorder is close to being 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.

VQW-765

- 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.

GAAP Financial Results

Net income was $2.6 million in the second quarter of 2022 compared to net income of $9.7 million in the second quarter of 2021. Diluted net income per share was $0.05 in the second quarter of 2022 compared to diluted net income per share of $0.17 in the second quarter of 2021.

Net loss was $3.9 million in the first six months of 2022 compared to net income of $18.3 million in the first six months of 2021. Diluted net loss per share was $0.07 in the first six months of 2022 compared to diluted net income per share of $0.32 in the first six months of 2021.

2022 Financial Guidance

Vanda expects to achieve the following financial objectives in 2022:

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

Conference Call

Vanda has scheduled a conference call for today, Wednesday, August 3, 2022, at 4:30 PM ET. During the call, Vanda's management will discuss the second 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 4304469. A replay of the call will be available on Wednesday, August 3, 2022, beginning at 8:30 PM ET and will be accessible until Wednesday, August 10, 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 4304469.

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 tradipitant in the treatment of gastroparesis and HETLIOZ® in the treatment of insomnia, Vanda's strategy for improving access to HETLIOZ® for all Non-24 patients, the timing of the court's decision with respect to the Company's HETLIOZ® patent litigation, and the clinical development timelines for 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., 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®, Vanda's ability to fully enroll and complete the Phase III clinical study of Fanapt® in bipolar disorder and Vanda's ability to complete the Phase II clinical study of VQW-765 in social/performance anxiety. 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		Six Months Ended	
	June 30 2022	June 30 2021	June 30 2022	June 30 2021
Revenues:				
HETLIOZ® net product sales	$ 41,188	$ 44,509	$ 78,219	$ 83,852
Fanapt® net product sales	23,202	23,390	46,363	46,716
Total revenues	64,390	67,899	124,582	130,568
Operating expenses:				
Cost of goods sold excluding amortization	6,059	6,566	11,724	12,596
Research and development	21,490	20,248	42,459	36,379
Selling, general and administrative	33,001	28,347	73,849	58,144
Intangible asset amortization	379	369	758	739
Total operating expenses	60,929	55,530	128,790	107,858
Income (loss) from operations	3,461	12,369	(4,208)	22,710
Other income	329	235	434	322
Income (loss) before income taxes	3,790	12,604	(3,774)	23,032
Provision for income taxes	1,216	2,951	82	4,729
Net income (loss)	$ 2,574	$ 9,653	$ (3,856)	$ 18,303
Net income (loss) per share, basic	$ 0.05	$ 0.17	$ (0.07)	$ 0.33
Net income (loss) per share, diluted	$ 0.05	$ 0.17	$ (0.07)	$ 0.32
Weighted average shares outstanding, basic	56,508,533	55,582,916	56,307,999	55,365,558
Weighted average shares outstanding, diluted	56,821,024	56,903,340	56,307,999	56,705,419

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

	June 30 2022	December 31 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,226	$ 52,071
Marketable securities	382,632	380,742
Accounts receivable, net	28,805	32,467
Inventory	1,496	1,025
Prepaid expenses and other current assets	25,736	11,996
Total current assets	496,895	478,301
Property and equipment, net	2,746	3,113
Operating lease right-of-use assets	8,603	9,272
Intangible assets, net	19,323	20,081
Deferred tax assets	72,687	74,878
Non-current inventory and other	8,848	8,147
Total assets	$ 609,102	$ 593,792
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 50,236	$ 34,438
Product revenue allowances	38,164	39,981
Total current liabilities	88,400	74,419
Operating lease non-current liabilities	9,286	10,055
Other non-current liabilities	2,867	4,390
Total liabilities	100,553	88,864
Stockholders' equity:		
Common stock	57	56
Additional paid-in capital	677,955	669,223
Accumulated other comprehensive loss	(1,431)	(175)
Accumulated deficit	(168,032)	(164,176)
Total stockholders' equity	508,549	504,928
Total liabilities and stockholders' equity	$ 609,102	$ 593,792

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