Vanda Pharmaceuticals Reports Second Quarter 2023 Financial Results

July 27, 2023

- *Q2 2023 total revenues were $46.1 million*
- *Total revenues in the first six months of 2023 were $108.6 million*
- *Vanda provides update on pipeline advancements and regulatory plans*

WASHINGTON, July 27, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2023.

"During the second quarter we continued our efforts to protect our commercial interests in the HETLIOZ® franchise in the face of the at-risk generic launch. We recorded a higher number of HETLIOZ® prescription dispenses in the second quarter of 2023 as compared to the first quarter of 2023, a testament to our dedication to our patient services and the loyalty of our patients," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "We also advanced towards our goal of marketing authorizations for Fanapt® in bipolar disorder, HETLIOZ® in insomnia and tradipitant in patients with gastroparesis."

Financial Highlights

Second Quarter of 2023

- Total net product sales from HETLIOZ® and Fanapt® were $46.1 million in the second quarter of 2023, a 28% decrease compared to $64.4 million in the second quarter of 2022.
- HETLIOZ® net product sales were $22.0 million in the second quarter of 2023, a 47% decrease compared to $41.2 million in the second quarter of 2022. The decrease was the result of the at-risk launch of a generic version of HETLIOZ® in the U.S.
- Fanapt® net product sales were $24.1 million in the second quarter of 2023, a 4% increase compared to $23.2 million in the second quarter of 2022.
- Net income was $1.5 million in the second quarter of 2023 compared to net income of $2.6 million in the second quarter of 2022.
- Cash, cash equivalents and marketable securities (Cash) was $489.4 million as of June 30, 2023, representing a decrease to Cash of $12.1 million, or 2%, compared to March 31, 2023.

First Six Months of 2023

- Total net product sales from HETLIOZ® and Fanapt® were $108.6 million in the first six months of 2023, a 13% decrease compared to $124.6 million in the first six months of 2022.
- HETLIOZ® net product sales were $61.6 million in the first six months of 2023, a 21% decrease compared to $78.2 million in the first six months of 2022. The decrease was the result of the at-risk launch of a generic version of HETLIOZ® in the U.S.
- Fanapt® net product sales were $47.0 million in the first six months of 2023, a 1% increase compared to $46.4 million in the first six months of 2022.
- Net income was $4.8 million in the first six months of 2023 compared to a net loss of $3.9 million in the first six months of 2022.
- Cash, cash equivalents and marketable securities (Cash) was $489.4 million as of June 30, 2023, representing an increase to Cash of $48.5 million, or 11%, compared to June 30, 2022.

Key Operational Highlights

Fanapt® (iloperidone)

- Vanda previously 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 continues to pursue U.S. Food and Drug Administration (FDA) approval of a supplemental New Drug Application (sNDA) for Fanapt® in bipolar I disorder.

HETLIOZ® (tasimelteon)

- Vanda is continuing to pursue FDA approvals for HETLIOZ® in the indications of insomnia and jet lag disorder.
- In May 2023, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit) affirmed the lower court ruling in favor of Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. and Apotex Corp. (Apotex) in the HETLIOZ® Abbreviated New Drug

Applications litigation. Vanda disagrees with the Federal Circuit's ruling, and in June 2023, Vanda requested a rehearing from the Federal Circuit. On July 18, 2023, the Federal Circuit requested a response from Teva and Apotex, which is due August 1, 2023.

Tradipitant

- Vanda continues to pursue FDA approval of a New Drug Application (NDA) for tradipitant for patients with gastroparesis.
- Vanda announced positive results in the Phase III study of tradipitant in motion sickness. Vanda plans to continue the motion sickness clinical program and pursue FDA approval upon completion of additional efficacy and safety studies.

Early-Stage Programs

- Vanda announced that the FDA had granted Orphan Drug Designation for VCA-894A for the treatment of Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), caused by cryptic splice site variants within IGHMBP2.

GAAP Financial Results

Net income was $1.5 million in the second quarter of 2023 compared to net income of $2.6 million in the second quarter of 2022. Diluted net income per share was $0.03 in the second quarter of 2023 compared to diluted net income per share of $0.05 in the second quarter of 2022.

Net income was $4.8 million in the first six months of 2023 compared to a net loss of $3.9 million in the first six months of 2022. Diluted net income per share was $0.08 in the first six months of 2023 compared to diluted net loss per share of $0.07 in the first six months of 2022.

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 and the at-risk launch of a generic version of HETLIOZ®, 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.

HETLIOZ® net product sales will likely decline in future periods, potentially significantly, related to the at-risk launch of a generic version of HETLIOZ® in the U.S.

Conference Call

Vanda has scheduled a conference call for today, Thursday, July 27, 2023, at 4:30 PM ET. During the call, Vanda's management will discuss the second quarter 2023 financial results and other corporate activities. Investors can call 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and use passcode number 4063687. A replay of the call will be available on Thursday, July 27, 2023, beginning at 8:30 PM ET and will be accessible until Thursday, August 3, 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 4063687.

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 FDA approval of Fanapt® in the treatment of bipolar I in adults, HETLIOZ® in the treatments of insomnia and jet lag disorder and tradipitant in the treatment of patients with gastroparesis and the treatment of motion sickness and Vanda's expectations regarding the impact of generic competition on the HETLIOZ® business 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 pursue and obtain FDA approval of the sNDAs for Fanapt® and HETLIOZ® and the NDA for tradipitant, the FDA's assessment of the sufficiency of the data packages to be included in Vanda's regulatory submissions for Fanapt®, HETLIOZ® and tradipitant, Vanda's ability to complete the clinical program for tradipitant in the treatment of motion sickness, the outcome of Vanda's request for a rehearing by the Federal Circuit and Vanda's ability to enforce its legal rights to exclusivity for HETLIOZ®. 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		Six Months Ended	
	June 30 2023	June 30 2022	June 30 2023	June 30 2022
Revenues:				
HETLIOZ® net product sales	$ 21,979	$ 41,188	$ 61,595	$ 78,219
Fanapt® net product sales	24,077	23,202	46,959	46,363
Total revenues	46,056	64,390	108,554	124,582
Operating expenses:				
Cost of goods sold excluding amortization	3,499	6,059	8,273	11,724
Research and development	16,647	21,490	35,884	42,459
Selling, general and administrative	28,399	33,001	64,503	73,849
Intangible asset amortization	378	379	757	758
Total operating expenses	48,923	60,929	109,417	128,790
Income (loss) from operations	(2,867)	3,461	(863)	(4,208)
Other income	5,459	329	8,983	434
Income (loss) before income taxes	2,592	3,790	8,120	(3,774)
Provision for income taxes	1,072	1,216	3,348	82
Net income (loss)	$ 1,520	$ 2,574	$ 4,772	$ (3,856)
Net income (loss) per share, basic	$ 0.03	$ 0.05	$ 0.08	$ (0.07)
Net income (loss) per share, diluted	$ 0.03	$ 0.05	$ 0.08	$ (0.07)
Weighted average shares outstanding, basic	57,453,916	56,508,533	57,233,878	56,307,999
Weighted average shares outstanding, diluted	57,535,615	56,821,024	57,469,105	56,307,999

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

	June 30 2023	December 31 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 150,031	$ 135,029
Marketable securities	339,320	331,830
Accounts receivable, net	33,621	33,512
Inventory	1,080	1,194
Prepaid expenses and other current assets	9,452	17,727
Total current assets	533,504	519,292
Property and equipment, net	2,164	2,573
Operating lease right-of-use assets	7,782	8,400
Intangible assets, net	17,808	18,565
Deferred tax assets	70,476	74,039
Non-current inventory and other	9,948	11,378
Total assets	$ 641,682	$ 634,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 31,929	$ 45,551
Product revenue allowances	55,468	45,885
Total current liabilities	87,397	91,436
Operating lease non-current liabilities	7,942	8,813
Other non-current liabilities	6,445	6,800
Total liabilities	101,784	107,049
Stockholders' equity:		

Common stock	57	57
Additional paid-in capital	693,835	686,235
Accumulated other comprehensive loss	(865)	(1,193)
Accumulated deficit	(153,129)	(157,901)
Total stockholders' equity	539,898	527,198
Total liabilities and stockholders' equity	$ 641,682	$ 634,247

Corporate Contact:
Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Elizabeth Van Every
Head of Corporate Affairs
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-second-quarter-2023-financial-results-301887779.html

SOURCE Vanda Pharmaceuticals Inc.

/