Vanda Pharmaceuticals Reports Third Quarter 2023 Financial Results

November 8, 2023

- *Total revenues in the first nine months of 2023 were $147.4 million*
- *Vanda provides update on pipeline advancements and regulatory plans*

WASHINGTON, Nov. 8, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2023.

"We have significantly advanced our development pipeline, now expecting FDA decisions on two sNDAs for bipolar I disorder and insomnia with PDUFA dates in the first half of 2024. We are also pleased with our revenue performance despite the challenges with the at-risk launch of a generic Hetlioz product," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "We look forward to increasing and diversifying our future revenue sources with new products and new indications on existing products as well as with external business development activities."

Financial Highlights

Third Quarter of 2023

- Total net product sales from HETLIOZ® and Fanapt® were $38.8 million in the third quarter of 2023, a 41% decrease compared to $65.3 million in the third quarter of 2022.
- HETLIOZ® net product sales were $17.5 million in the third quarter of 2023, a 58% decrease compared to $41.3 million in the third 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 $21.3 million in the third quarter of 2023, an 11% decrease compared to $24.0 million in the third quarter of 2022.
- Net income was $0.1 million in the third quarter of 2023 compared to net income of $3.3 million in the third quarter of 2022.
- Cash, cash equivalents and marketable securities (Cash) was $489.9 million as of September 30, 2023, representing an increase to Cash of $0.5 million compared to June 30, 2023.

First Nine Months of 2023

- Total net product sales from HETLIOZ® and Fanapt® were $147.4 million in the first nine months of 2023, a 22% decrease compared to $189.9 million in the first nine months of 2022.
- HETLIOZ® net product sales were $79.1 million in the first nine months of 2023, a 34% decrease compared to $119.6 million in the first nine 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 $68.3 million in the first nine months of 2023, a 3% decrease compared to $70.3 million in the first nine months of 2022.
- Net income was $4.9 million in the first nine months of 2023 compared to a net loss of $0.6 million in the first nine months of 2022.
- Cash, cash equivalents and marketable securities (Cash) was $489.9 million as of September 30, 2023, representing an increase to Cash of $35.1 million, or 8%, compared to September 30, 2022.

Key Operational Highlights

Fanapt® (iloperidone)

- The supplemental New Drug Application (sNDA) for Fanapt® in bipolar I disorder in adults was accepted for filing by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of April 2, 2024.

HETLIOZ® (tasimelteon)

- The sNDA for HETLIOZ® in insomnia was accepted for filing by the FDA with a PDUFA target action date of March 4, 2024. Vanda is continuing to pursue FDA approval for HETLIOZ® in jet lag disorder.
- Vanda intends to file a petition to the U.S. Supreme Court for a writ of certiorari in its HETLIOZ® Abbreviated New Drug Application (ANDA) litigation against Teva Pharmaceuticals USA, Inc., Apotex Inc. and Apotex Corp. Chief Justice Roberts extended the time for the filing of Vanda's forthcoming petition, which Vanda expects to file by January 12, 2024.

Tradipitant

- Vanda continues to pursue FDA approval of a New Drug Application (NDA) for tradipitant for patients with gastroparesis.
- Vanda initiated a second Phase III study of tradipitant in motion sickness and the study is over 20% enrolled. Vanda previously announced positive results in its first Phase III study of tradipitant in motion sickness. Vanda plans to pursue FDA approval upon completion of the clinical development program.

GAAP Financial Results

Net income was $0.1 million in the third quarter of 2023 compared to net income of $3.3 million in the third quarter of 2022. Diluted net income per share was $0.00 in the third quarter of 2023 compared to diluted net income per share of $0.06 in the third quarter of 2022.

Net income was $4.9 million in the first nine months of 2023 compared to a net loss of $0.6 million in the first nine months of 2022. Diluted net income per share was $0.09 in the first nine months of 2023 compared to diluted net loss per share of $0.01 in the first nine 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.

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, Wednesday, November 8, 2023, at 4:30 PM ET. During the call, Vanda's management will discuss the third 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 9774278. A replay of the call will be available on Wednesday, November 8, 2023, beginning at 8:30 PM ET and will be accessible until Wednesday, November 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 9774278.

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, Vanda's expectations regarding the timing of the FDA's decisions with respect to the sNDAs for Fanapt® and HETLIOZ®, Vanda's plans to increase and diversify its sources of revenue, Vanda's intention to petition the U.S. Supreme Court for a writ of certiorari in connection with its ANDA litigation and Vanda's expectations regarding the timing thereof 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 ability to meet the PDUFA target action dates for the sNDAs for Fanapt® and HETLIOZ®, the FDA's assessment of the sufficiency of the data packages included in Vanda's regulatory submissions for Fanapt®, HETLIOZ® and tradipitant, Vanda's ability to develop and/or acquire new products and obtain FDA approval of new indications for its existing products, Vanda's ability to complete the clinical program for tradipitant in the treatment of motion sickness, Vanda's ability to file its petition for a writ of certiorari with the U.S. Supreme Court on or before January 12, 2024 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		Nine Months Ended	
	September 30 2023	September 30 2022	September 30 2023	September 30 2022
Revenues:				
HETLIOZ® net product sales	$ 17,500	$ 41,335	$ 79,095	$ 119,554
Fanapt® net product sales	21,315	23,983	68,274	70,346
Total revenues	38,815	65,318	147,369	189,900
Operating expenses:				
Cost of goods sold excluding amortization	3,063	6,320	11,336	18,044
Research and development	16,600	24,857	52,484	67,316
Selling, general and administrative	24,767	29,854	89,270	103,703
Intangible asset amortization	380	379	1,137	1,137
Total operating expenses	44,810	61,410	154,227	190,200
Income (loss) from operations	(5,995)	3,908	(6,858)	(300)
Other income	5,875	1,553	14,858	1,987
Income (loss) before income taxes	(120)	5,461	8,000	1,687
Provision (benefit) for income taxes	(257)	2,191	3,091	2,273
Net income (loss)	$ 137	$ 3,270	$ 4,909	$ (586)
Net income (loss) per share, basic	$ 0.00	$ 0.06	$ 0.09	$ (0.01)
Net income (loss) per share, diluted	$ 0.00	$ 0.06	$ 0.09	$ (0.01)
Weighted average shares outstanding, basic	57,519,031	56,574,503	57,329,969	56,397,805
Weighted average shares outstanding, diluted	57,595,344	56,969,033	57,512,225	56,397,805

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

	September 30 2023	December 31 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 183,186	$ 135,029
Marketable securities	306,672	331,830
Accounts receivable, net	29,272	33,512
Inventory	1,006	1,194
Prepaid expenses and other current assets	16,436	17,727
Total current assets	536,572	519,292
Property and equipment, net	2,128	2,573
Operating lease right-of-use assets	7,428	8,400
Intangible assets, net	17,428	18,565
Deferred tax assets	67,772	74,039
Non-current inventory and other	10,277	11,378
Total assets	$ 641,605	$ 634,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 32,595	$ 45,551
Product revenue allowances	52,242	45,885
Total current liabilities	84,837	91,436
Operating lease non-current liabilities	7,472	8,813
Other non-current liabilities	6,196	6,800
Total liabilities	98,505	107,049
Stockholders' equity:		
Common stock	58	57
Additional paid-in capital	697,001	686,235
Accumulated other comprehensive loss	(967)	(1,193)
Accumulated deficit	(152,992)	(157,901)
Total stockholders' equity	543,100	527,198

Total liabilities and stockholders' equity	$ 641,605	$ 634,247

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

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