Vanda Pharmaceuticals Reports First Quarter 2023 Financial Results

May 3, 2023

- *Q1 2023 total revenues were $62.5 million*
- *Vanda provides update on three upcoming regulatory submissions*

WASHINGTON, May 3, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2023.

"The first quarter of 2023 was busy and challenging as we are preparing three regulatory submissions for bipolar disorder, insomnia and gastroparesis and, at the same time, defending our intellectual property," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board.

Financial Highlights

- Total net product sales from HETLIOZ® and Fanapt® were $62.5 million in the first quarter of 2023, a 4% increase compared to $60.2 million in the first quarter of 2022.
- HETLIOZ® net product sales were $39.6 million in the first quarter of 2023, a 7% increase compared to $37.0 million in the first quarter of 2022. Net product sales for the first quarter of 2023 reflect significant inventory stocking at specialty pharmacy customers as compared to prior periods related to the at-risk launch of a generic version of HETLIOZ® in the U.S.
- Fanapt® net product sales were $22.9 million in the first quarter of 2023, a 1% decrease compared to $23.2 million in the first quarter of 2022.
- Net income was $3.3 million in the first quarter of 2023 compared to a net loss of $6.4 million in the first quarter of 2022.
- Cash, cash equivalents and marketable securities (Cash) was $501.5 million as of March 31, 2023, representing an increase to Cash of $66.3 million, or 15%, compared to March 31, 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 expects to submit a supplemental New Drug Application (sNDA) in the second quarter of 2023.

HETLIOZ® (tasimelteon)

- Vanda is continuing to pursue regulatory approvals for HETLIOZ® in the indications of insomnia and jet lag disorder.
- On March 14, 2023, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit) held an oral argument in relation to Vanda's appeal of the HETLIOZ® Abbreviated New Drug Application litigation ruling in favor of defendants Teva Pharmaceuticals USA, Inc., Apotex Inc. and Apotex Corp. Vanda awaits the Federal Circuit's decision.
- In March 2023, Vanda announced that it had prevailed against the U.S. Food and Drug Administration (FDA) in a Freedom of Information Act lawsuit regarding certain records relating to the FDA's denial of Vanda's sNDA for HETLIOZ® in jet lag disorder.

Tradipitant

- Vanda is preparing for the submission of a New Drug Application (NDA) for tradipitant for patients with gastroparesis. Vanda expects to submit this NDA to the FDA in the second quarter of 2023.
- The Phase III study of tradipitant in the treatment of motion sickness is fully enrolled. Results are expected by mid-2023.

GAAP Financial Results

Net income was $3.3 million in the first quarter of 2023 compared to net loss of $6.4 million in the first quarter of 2022. Diluted net income per share was $0.06 in the first quarter of 2023 compared to diluted net loss per share of $0.11 in the first quarter 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, Wednesday, May 3, 2023, at 4:30 PM ET. During the call, Vanda's management will discuss the first 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 7072297. A replay of the call will be available on Wednesday, May 3, 2023, beginning at 8:30 PM ET and will be accessible until Wednesday, May 10, 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 7072297.

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 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, the clinical development timeline for tradipitant in 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 obtain regulatory approval for HETLIOZ® in the indications of insomnia and jet lag disorder, Vanda's ability to complete and submit the sNDA for Fanapt® and NDA for tradipitant in the specified timeframes, the FDA's assessment of the sufficiency of the data packages to be included in Vanda's planned regulatory submissions for Fanapt®, HETLIOZ® and tradipitant, Vanda's ability to complete the Phase III clinical study of tradipitant in the treatment of motion sickness by mid-2023, the outcome of Vanda's appeal in 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	
	March 31 2023	**March 31 2022**
Revenues:		
HETLIOZ® net product sales	$ 39,616	$ 37,031
Fanapt® net product sales	22,882	23,161
Total revenues	62,498	60,192
Operating expenses:		
Cost of goods sold excluding amortization	4,774	5,665
Research and development	19,237	20,969
Selling, general and administrative	36,104	40,848
Intangible asset amortization	379	379
Total operating expenses	60,494	67,861
Income (loss) from operations	2,004	(7,669)
Other income	3,524	105

Income (loss) before income taxes	5,528	(7,564)
Provision (benefit) for income taxes	2,276	(1,134)
Net income (loss)	$ 3,252	$ (6,430)
Net income (loss) per share, basic	$ 0.06	$ (0.11)
Net income (loss) per share, diluted	$ 0.06	$ (0.11)
Weighted average shares outstanding, basic	57,011,396	56,105,239
Weighted average shares outstanding, diluted	57,400,152	56,105,239

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

	March 31 2023	December 31 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 354,171	$ 135,029
Marketable securities	147,325	331,830
Accounts receivable, net	24,513	33,512
Inventory	1,105	1,194
Prepaid expenses and other current assets	6,593	17,727
Total current assets	533,707	519,292
Property and equipment, net	2,333	2,573
Operating lease right-of-use assets	8,097	8,400
Intangible assets, net	18,186	18,565
Deferred tax assets	71,747	74,039
Non-current inventory and other	10,462	11,378
Total assets	$ 644,532	$ 634,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 35,092	$ 45,551
Product revenue allowances	58,702	45,885
Total current liabilities	93,794	91,436
Operating lease non-current liabilities	8,387	8,813
Other non-current liabilities	6,612	6,800
Total liabilities	108,793	107,049
Stockholders' equity:		
Common stock	57	57
Additional paid-in capital	690,586	686,235
Accumulated other comprehensive loss	(255)	(1,193)
Accumulated deficit	(154,649)	(157,901)
Total stockholders' equity	535,739	527,198
Total liabilities and stockholders' equity	$ 644,532	$ 634,247

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