Vanda Pharmaceuticals Reports First Quarter 2021 Financial Results

May 5, 2021

- Q1 2021 total revenues were $62.7 million, an 8% increase compared to Q1 2020

- The Phase III clinical study of tradipitant in gastroparesis is expected to complete enrollment in the second quarter of 2021

- A Phase III clinical study for HETLIOZ® in delayed sleep phase disorder (DSPD) was initiated in the first quarter of 2021

WASHINGTON, May 5, 2021 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2021.

"Despite seasonal and global challenges, we recorded another quarter of strong revenue across our commercial portfolio coupled with the launch of HETLIOZ® in the new indication of nighttime sleep disturbances in patients with Smith-Magenis Syndrome," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. "In our clinical programs, we have made significant progress, reaching 85% randomization in our Phase III tradipitant study in gastroparesis and initiating a new clinical program for HETLIOZ® in delayed sleep phase disorder."

Financial Highlights

- Total net product sales from HETLIOZ® and Fanapt® were $62.7 million in the first quarter of 2021, an 8% increase compared to $58.0 million in the first quarter of 2020.
- HETLIOZ® net product sales were $39.3 million in the first quarter of 2021, an 11% increase compared to $35.3 million in the first quarter of 2020.
- Fanapt® net product sales were $23.3 million in the first quarter of 2021, a 3% increase compared to $22.7 million in the first quarter of 2020.
- Income before taxes was $10.4 million in the first quarter of 2021 compared to $1.2 million in the first quarter of 2020.
- Cash, cash equivalents and marketable securities (Cash) was $378.2 million as of March 31, 2021, representing an increase to Cash of $65.8 million compared to March 31, 2020.

Key Operational Highlights

Tradipitant

- The gastroparesis Phase III clinical study (VP-VLY-686-3301) is ongoing. The study has a target enrollment of 200 randomized patients and is expected to complete enrollment in the second quarter of 2021, with a New Drug Application (NDA) filing expected in late 2021 or early 2022.

HETLIOZ® (tasimelteon)

- In December 2020, the U.S. Food and Drug Administration (FDA) approved HETLIOZ® capsule and liquid formulations for the treatment of adults and children, respectively, with nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).[1] HETLIOZ® capsules, for adults with SMS, were immediately available after approval and the HETLIOZ LQ ™ liquid formulation, for children with SMS, became available in the first quarter of 2021.
- A Phase III clinical study of HETLIOZ® in delayed sleep phase disorder (DSPD) was initiated in the first quarter of 2021.

Fanapt® (iloperidone)

- A Phase III clinical study of Fanapt® in bipolar disorder resumed during the first quarter of 2021 after pausing in 2020 due to the COVID-19 pandemic.
- Development of the long acting injectable (LAI) formulation of Fanapt® is ongoing.
- A clinical development program of Fanapt® in Parkinson's disease psychosis (PDP) was initiated in the first quarter of 2021.

GAAP Financial Results

Income before taxes was $10.4 million in the first quarter of 2021 compared to $1.2 million in the first quarter of 2020. Net income was $8.7 million in the first quarter of 2021 compared to net income of $0.5 million in the first quarter of 2020. Diluted net income per share was $0.15 in the first quarter of 2021 compared to diluted net income per share of $0.01 in the first quarter of 2020.

2021 Financial Guidance

Vanda expects to achieve the following financial objectives in 2021:

Full Year 2021 Financial Objectives	Full Year 2021 Guidance
Total revenues	$270 to $300 million
HETLIOZ® net product sales	$180 to $200 million
Fanapt® net product sales	$90 to $100 million
Year-end 2021 Cash	Greater than $400 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, May 5, 2021, at 4:30 PM ET. During the call, Vanda's management will discuss the first quarter 2021 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 5709209. A replay of the call will be available on Wednesday, May 5, 2021, beginning at 7:30 PM ET and will be accessible until Wednesday, May 12, 2021 at 7:30 PM ET. The replay call-in number is 1-855-859-2056 for domestic callers and 1-404-537-3406 for international callers. The passcode number is 5709209.

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.

References

1. Refer to Company press release titled "FDA Approves HETLIOZ® (tasimelteon) for the Treatment of Nighttime Sleep Disturbances in Smith-Magenis Syndrome" issued on December 1, 2020. https://vandapharmaceuticalsinc.gcs-web.com/node/14306/pdf

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 "2021 Financial Guidance" above and statements regarding the clinical development and regulatory timelines for tradipitant 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 its ability to continue to grow its business in the U.S. and Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis. 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, 2020, 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 2021	March 31 2020
Revenues:		
HETLIOZ® net product sales	$ 39,343	$ 35,336
Fanapt® net product sales	23,326	22,664
Total revenues	62,669	58,000
Operating expenses:		
Cost of goods sold excluding amortization	6,030	5,207
Research and development	16,131	15,527
Selling, general and administrative	29,797	37,021
Intangible asset amortization	370	370
Total operating expenses	52,328	58,125
Income (loss) from operations	10,341	(125)
Other income	87	1,366

Income before income taxes	10,428	1,241
Provision for income taxes	1,778	755
Net income	$ 8,650	$ 486
Net income per share, basic	$ 0.16	$ 0.01
Net income per share, diluted	$ 0.15	$ 0.01
Weighted average shares outstanding, basic	55,145,789	53,806,317
Weighted average shares outstanding, diluted	56,505,087	54,870,146

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

	March 31 2021	December 31 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 72,132	$ 61,031
Marketable securities	306,030	306,709
Accounts receivable, net	31,474	30,036
Inventory	1,361	1,280
Prepaid expenses and other current assets	10,227	10,089
Total current assets	421,224	409,145
Property and equipment, net	3,840	4,136
Operating lease right-of-use assets	10,194	10,459
Intangible assets, net	21,189	21,559
Deferred tax assets	80,355	81,516
Non-current inventory and other	6,389	6,641
Total assets	$ 543,191	$ 533,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 26,105	$ 31,509
Product revenue allowances	35,679	34,427
Total current liabilities	61,784	65,936
Operating lease non-current liabilities	11,125	11,497
Other non-current liabilities	2,655	2,757
Total liabilities	75,564	80,190
Stockholders' equity:		
Common stock	56	55
Additional paid-in capital	656,057	650,300
Accumulated other comprehensive income	192	239
Accumulated deficit	(188,678)	(197,328)
Total stockholders' equity	467,627	453,266
Total liabilities and stockholders' equity	$ 543,191	$ 533,456

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