Vanda Pharmaceuticals Reports Second Quarter 2020 Financial Results

August 5, 2020

- Q2 2020 Total net product sales reached a new record of $62.2 million, a 7% increase as compared to Q1 2020

- Q2 2020 HETLIOZ® net product sales reached a new record of $41.6 million, an 18% increase as compared to Q1 2020

- The HETLIOZ® SMS marketing authorization applications were accepted for priority review by the FDA

WASHINGTON, Aug. 5, 2020 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2020.

"We are very proud of the achievements of our team, especially the record commercial performance, even in the face of the challenges presented by the pandemic. We are also very excited with the progress of the HETLIOZ® SMS applications as we get closer to providing a therapeutic solution to patients with SMS," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO.

Key Financial and Corporate Highlights

- Total revenues from HETLIOZ® and Fanapt® were $62.2 million in the second quarter of 2020, a 5% increase compared to $59.1 million in the second quarter of 2019.
- HETLIOZ® net product sales were $41.6 million in the second quarter of 2020, a 10% increase compared to $37.8 million in the second quarter of 2019.
- Fanapt® net product sales were $20.6 million in the second quarter of 2020, a 3% decrease compared to $21.2 million in the second quarter of 2019.
- Cash, cash equivalents and marketable securities (Cash) were $339.8 million as of June 30, 2020, representing an increase to Cash of $47.2 million compared to June 30, 2019.
- Net income was $8.7 million in the second quarter of 2020 compared to net income of $11.5 million in the second quarter of 2019.

Key Product and Pipeline Highlights

Products

Vanda is encouraged by its record commercial performance during the second quarter of 2020. Vanda continues to implement marketing and sales strategies aimed at supporting continued growth and minimizing the impact of disruptions caused by the COVID-19 pandemic, including the launch of a Fanapt® for schizophrenia direct-to-consumer campaign at the end of the second quarter of 2020.

Pipeline

The COVID-19 pandemic has impacted clinical research globally, including Vanda's previously reported clinical trials. The tradipitant gastroparesis and motion sickness programs have resumed, while recruitment for the tradipitant atopic dermatitis program, as well as the HETLIOZ® delayed sleep phase disorder study and Fanapt® bipolar disorder and long acting injectable studies, is currently on hold.

Tradipitant

- An Individual Patient Expanded Access protocol (VP-VLY-686-3303) for tradipitant in gastroparesis was approved by the U.S. Food and Drug Administration (FDA) and the patient was enrolled in July 2020. Under this protocol, this patient will receive tradipitant treatment for a period of up to six months, which may be extended upon review by the FDA.
- The gastroparesis Phase III clinical study (VP-VLY-686-3301) resumed recruitment. Enrollment in this 200-person study is expected to be completed in the first half of 2021 with a New Drug Application (NDA) filing projected for later that year.
- The protocol for the pivotal Phase III motion sickness study was discussed with the FDA at the end of Phase II meeting, and the FDA agrees with the adequacy of the program design to support an application. Preparations for this study have begun with the boat trip portion of the study expected to commence as soon as local restrictions are lifted.
- Patient enrollment in the Phase III clinical study (ODYSSEY VLY-686-3501) of tradipitant in COVID-19 Acute Respiratory Distress Syndrome (ARDS) is ongoing and an interim analysis will be conducted to determine next steps.

HETLIOZ® (tasimelteon)

- The Smith-Magenis Syndrome (SMS) marketing authorization applications were accepted by the FDA for priority review with a Prescription Drug User Fee Act (PDUFA-VI) target action date of December 1, 2020.[1]
- The FDA appeals process related to the sNDA for HETLIOZ® for the treatment of jet lag disorder is ongoing.

Key Publications

- The article "Efficacy and Safety of Tradipitant in Patients with Diabetic and Idiopathic Gastroparesis in a Randomized, Placebo-Controlled Trial" was accepted for publication in the July 2020 issue of *Gastroenterology*.[2]
- The article "Efficacy of Tasimelteon (HETLIOZ®) in the Treatment of Jet Lag Disorder Evaluated in an 8-h Phase Advance Model; a Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial" was published in the July 2020 issue of *Frontiers in Neurology*.[3]

GAAP Financial Results

Net income was $8.7 million in the second quarter of 2020, compared to net income of $11.5 million in the second quarter of 2019. Diluted net income per share was $0.16 in the second quarter of 2020, compared to diluted net income per share of $0.21 in the second quarter of 2019.

2020 Financial Guidance

Vanda will continue to assess the impact of the evolving pandemic on its business and operations and will provide future updates to its financial guidance as necessary. The financial guidance previously communicated by Vanda is shown below. In addition, Vanda provides an update to Year-end 2020 Cash.

Full Year 2020 Financial Objectives	Full Year 2020 Guidance
Total revenues	$240 to $260 million
HETLIOZ® net product sales	$155 to $165 million
Fanapt® net product sales	$85 to $95 million
Year-end 2020 Cash	Greater than $340 million as compared to prior guidance of greater than $320 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, August 5, 2020, at 4:30 PM ET. During the call, Vanda's management will discuss the second quarter 2020 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 49854840.

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 Accepts and Grants Priority Review of Vanda's Applications for HETLIOZ® (tasimelteon) in the Treatment of Smith-Magenis Syndrome" issued on August 3, 2020. https://vandapharmaceuticalsinc.gcs-web.com/node/14226/pdf

[2] Carlin, J. L., Lieberman, V. R., Dahal, A., Keefe, M. S., Xiao, C., Birznieks, G., Abell, T. L., Lembo, A., Parkman, H., & Polymeropoulos, M. H. (2020). Efficacy and safety of tradipitant in patients with diabetic and idiopathic gastroparesis in a randomized, placebo-controlled trial. *Gastroenterology*. Advance online publication. https://doi.org/10.1053/j.gastro.2020.07.029

[3] Polymeropoulos, C. M., Mohrman, M. A., Keefe, M. S., Brzezynski, J. L., Wang, J., Prokosch, L. S., Polymeropoulos, V. M., Xiao, C., Birznieks, G., & Polymeropoulos, M. H. (2020). Efficacy of tasimelteon (Hetlioz®) in the treatment of jet lag disorder evaluated in an 8-h phase advance model; a multicenter, randomized, double-blind, placebo-controlled trial. *Frontiers in Neurology*, 11, 611. https://doi.org/10.3389/fneur.2020.00611

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 "2020 Financial Guidance" above and statements regarding Vanda's ability to make HETLIOZ® available to patients with SMS, Vanda's marketing and sales strategies, the Individual Patient Expanded Access protocol for tradipitant, recruitment for the gastroparesis, motion sickness and ODYSSEY studies and clinical development and regulatory timelines for tradipitant and HETLIOZ® are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions 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.; Vanda's ability to minimize the disruption caused by, and maintain business continuity during, the global COVID-19 pandemic and related market volatility; the duration and severity of the global COVID-19 pandemic, including prevailing economic

conditions and general uncertainties relating thereto that may be unknown and unforeseeable; Vanda's ability to enroll patients in and complete its gastroparesis, motion sickness and ODYSSEY studies; Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis, motion sickness, atopic dermatitis and COVID-19 ARDS; Vanda's ability to successfully resume the clinical programs that are currently on hold and the FDA's ability to complete its review of the HETLIOZ® applications for the treatment of SMS on time and make the determination that HETLIOZ® is safe and effective in the treatment of SMS in adults and children. There can be no assurance that the actual 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. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved. 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, 2019, 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 2020	June 30 2019	June 30 2020	June 30 2019
Revenues:				
HETLIOZ® net product sales	$ 41,561	$ 37,835	$ 76,897	$ 66,792
Fanapt® net product sales	20,646	21,225	43,310	39,981
Total revenues	62,207	59,060	120,207	106,773
Operating expenses:				
Cost of goods sold excluding amortization	5,847	6,368	11,054	11,481
Research and development	12,903	10,950	28,430	24,228
Selling, general and administrative	33,917	31,468	70,938	62,497
Intangible asset amortization	369	379	739	759
Total operating expenses	53,036	49,165	111,161	98,965
Income from operations	9,171	9,895	9,046	7,808
Other income	1,918	1,649	3,284	3,134
Income before income taxes	11,089	11,544	12,330	10,942
Provision for income taxes	2,375	18	3,130	28
Net income	$ 8,714	$ 11,526	$ 9,200	$ 10,914
Net income per share, basic	$ 0.16	$ 0.22	$ 0.17	$ 0.21
Net income per share, diluted	$ 0.16	$ 0.21	$ 0.17	$ 0.20
Weighted average shares outstanding, basic	54,501,308	53,101,499	54,153,812	52,928,101
Weighted average shares outstanding, diluted	55,081,397	54,579,982	54,975,771	54,932,932

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

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,305	$ 45,072
Marketable securities	244,544	267,057
Accounts receivable, net	24,587	26,367
Inventory	1,384	1,140
Prepaid expenses and other current assets	15,041	14,500
Total current assets	380,861	354,136
Property and equipment, net	3,744	3,864

Operating lease right-of-use assets	10,601	11,180
Intangible assets, net	22,298	23,037
Deferred tax assets	85,558	87,680
Non-current inventory and other	3,569	3,851
Total assets	$506,631	$ 483,748

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	$ 28,398	$ 27,590
Product revenue allowances	33,194	31,915
Total current liabilities	61,592	59,505
Operating lease non-current liabilities	11,720	12,455
Other non-current liabilities	1,735	843
Total liabilities	75,047	72,803
Stockholders' equity:		
Common stock	55	54
Additional paid-in capital	642,398	631,307
Accumulated other comprehensive income	596	249
Accumulated deficit	(211,465)	(220,665)
Total stockholders' equity	431,584	410,945
Total liabilities and stockholders' equity	$506,631	$ 483,748

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