Vanda Pharmaceuticals Reports Third Quarter 2020 Financial Results

October 28, 2020

- Q3 2020 Total net product sales of $60.3 million, a 1% increase compared to Q3 2019

- Total net product sales for the first nine months of 2020 grew to $180.5 million, a 9% increase compared to the same period in 2019

- The HETLIOZ® Smith-Magenis Syndrome marketing authorization applications accepted by the FDA for priority review with a PDUFA-VI target action date of December 1, 2020

WASHINGTON, Oct. 28, 2020 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2020.

"Vanda continued to deliver strong commercial performance in the third quarter, despite the ongoing COVID-19 pandemic, while at the same time we advanced our robust clinical development pipeline," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO.

Key Financial and Corporate Highlights

Third Quarter of 2020

- Total net product sales from HETLIOZ® and Fanapt® were $60.3 million in the third quarter of 2020, a 1% increase compared to $59.5 million in the third quarter of 2019.
- HETLIOZ® net product sales were $39.6 million in the third quarter of 2020, a 5% increase compared to $37.6 million in the third quarter of 2019.
- Fanapt® net product sales were $20.7 million in the third quarter of 2020, a 6% decrease compared to $21.9 million in the third quarter of 2019.
- Income before taxes was $8.4 million in the third quarter of 2020 compared to $12.3 million in the third quarter of 2019.

First Nine Months of 2020

- Total net product sales from HETLIOZ® and Fanapt® were $180.5 million in the first nine months of 2020, a 9% increase compared to $166.3 million in the same period in 2019.
- HETLIOZ® net product sales were $116.5 million in the first nine months of 2020, a 12% increase compared to $104.4 million in the same period in 2019.
- Fanapt® net product sales were $64.0 million in the first nine months of 2020, a 3% increase compared to $61.9 million in the same period in 2019.
- Income before taxes was $20.7 million in the first nine months of 2020 compared to $23.2 million in the same period in 2019.
- Cash, cash equivalents and marketable securities (Cash) were $348.5 million as of September 30, 2020, representing an increase to Cash of $48.9 million compared to September 30, 2019.

Key Product and Pipeline Highlights

Products

Vanda is encouraged by the strength of its commercial performance during the third quarter of 2020 despite the COVID-19 pandemic. 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 Fanapt® for schizophrenia direct-to-consumer campaign, which was launched at the end of the second quarter of 2020.

Pipeline

The COVID-19 pandemic has impacted clinical research globally, including some of Vanda's previously reported clinical trials. The tradipitant gastroparesis program has resumed patient enrollment, while randomization for the tradipitant motion sickness and atopic dermatitis programs, as well as the Fanapt® bipolar disorder and long acting injectable studies, is currently on hold.

Tradipitant

- The gastroparesis Phase III clinical study (VP-VLY-686-3301) is ongoing. The study reached 50% enrollment towards a target of 200 randomized patients and is expected to complete enrollment in the first half of 2021 with a New Drug Application (NDA) filing projected for later that year.
- Interim analysis from the Phase III clinical study (ODYSSEY VLY-686-3501) shows that tradipitant may accelerate clinical improvement in patients with COVID-19 pneumonia.[1] Vanda continues to recruit patients for this study.

HETLIOZ® (tasimelteon)

- The Smith-Magenis Syndrome (SMS) marketing authorization applications were accepted by the U.S. Food and Drug Administration (FDA) for priority review with a Prescription Drug User Fee Act (PDUFA-VI) target action date of December 1, 2020.[2]

VSJ-110 (previously known as $CFTR_{act}$-K267)

- The Investigational New Drug (IND) application to evaluate Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activator VSJ-110 for the treatment of allergic conjunctivitis was approved by the FDA.[3]

Key Publications

- The article "Tradipitant in the Treatment of Motion Sickness: A Randomized, Double-Blind, Placebo-Controlled Study" was published in the September 2020 issue of *Frontiers in Neurology*.[4]

GAAP Financial Results

Income before taxes was $8.4 million in the third quarter of 2020 compared to $12.3 million in the third quarter of 2019. Net income was $5.9 million in the third quarter of 2020, compared to net income of $100.4 million in the third quarter of 2019. Diluted net income per share was $0.11 in the third quarter of 2020, compared to diluted net income per share of $1.84 in the third quarter of 2019.

Income before taxes was $20.7 million in the first nine months of 2020 compared to $23.2 million in the same period in 2019. Net income was $15.1 million in the first nine months of 2020, compared to net income of $111.3 million in the same period in 2019. Diluted net income per share was $0.28 in the first nine months of 2020, compared to diluted net income per share of $2.03 in the same period in 2019.

The income tax benefit of $88.1 million reflected in the financial results for both the third quarter of 2019 and the first nine months of 2019 includes the favorable impact of the release of Vanda's deferred tax asset valuation allowance.

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.

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

Conference Call

Vanda has scheduled a conference call for today, Wednesday, October 28, 2020, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 2020 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode number 8971955. A replay of the call will be available on Wednesday, October 28, 2020, beginning at 7:30 PM ET and will be accessible until Wednesday, November 4, 2020 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 8971955.

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 "Vanda Pharmaceuticals' Interim Analysis from ODYSSEY Study Shows Tradipitant may Accelerate Clinical Improvement in Patients with COVID-19 Pneumonia" issued on August 18, 2020. https://vandapharmaceuticalsinc.gcs-web.com/node/14256/pdf
2. 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
3. Refer to Company press release titled "Vanda Pharmaceuticals Receives FDA Approval to Proceed with Investigational New Drug VSJ-110 for Allergic Conjunctivitis" issued on October 26, 2020. https://vandapharmaceuticalsinc.gcs-web.com/node/14286/pdf
4. Polymeropoulos, V.M., Czeisler, M.E., Gibson, M.M., Anderson, A.A., Miglo, J., Wang, J., Xiao, C., Polymeropoulos, C.M., Birznieks, G., & Polymeropoulos, M. H. (2020). Tradipitant in the Treatment of Motion Sickness: A Randomized, Double-Blind, Placebo-Controlled Study. *Frontiers in Neurology*, 11, p. 563373. https://doi.org/10.3389/fneur.2020.563373

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 marketing and sales strategies, recruitment for the gastroparesis and ODYSSEY studies, the interim analysis from the ODYSSEY study 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 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 pneumonia; 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		Nine Months Ended	
	September 30 2020	September 30 2019	September 30 2020	September 30 2019
Revenues:				
HETLIOZ® net product sales	$ 39,618	$ 37,589	$ 116,515	$ 104,381
Fanapt® net product sales	20,690	21,896	64,000	61,877
Total revenues	60,308	59,485	180,515	166,258
Operating expenses:				
Cost of goods sold excluding amortization	5,898	6,782	16,952	18,263
Research and development	12,298	11,347	40,728	35,575
Selling, general and administrative	34,001	30,221	104,939	92,718
Intangible asset amortization	369	376	1,108	1,135
Total operating expenses	52,566	48,726	163,727	147,691
Income from operations	7,742	10,759	16,788	18,567
Other income	659	1,517	3,943	4,651
Income before income taxes	8,401	12,276	20,731	23,218
Provision (benefit) for income taxes	2,454	(88,147)	5,584	(88,119)
Net income	$ 5,947	$ 100,423	$ 15,147	$ 111,337
Net income per share, basic	$ 0.11	$ 1.88	$ 0.28	$ 2.10
Net income per share, diluted	$ 0.11	$ 1.84	$ 0.28	$ 2.03
Weighted average shares outstanding, basic	54,666,128	53,297,298	54,325,832	53,052,521
Weighted average shares outstanding, diluted	55,209,032	54,541,625	55,054,772	54,803,851

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

	September 30 2020	December 31 2019
ASSETS		

Current assets:		
Cash and cash equivalents	$ 56,973	$ 45,072
Marketable securities	291,575	267,057
Accounts receivable, net	28,033	26,367
Inventory	1,322	1,140
Prepaid expenses and other current assets	11,631	14,500
Total current assets	389,534	354,136
Property and equipment, net	3,921	3,864
Operating lease right-of-use assets	10,306	11,180
Intangible assets, net	21,929	23,037
Deferred tax assets	83,858	87,680
Non-current inventory and other	6,357	3,851
Total assets	$ 515,905	$ 483,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 29,086	$ 27,590
Product revenue allowances	32,273	31,915
Total current liabilities	61,359	59,505
Operating lease non-current liabilities	11,559	12,455
Other non-current liabilities	2,415	843
Total liabilities	75,333	72,803
Stockholders' equity:		
Common stock	55	54
Additional paid-in capital	645,656	631,307
Accumulated other comprehensive income	379	249
Accumulated deficit	(205,518)	(220,665)
Total stockholders' equity	440,572	410,945
Total liabilities and stockholders' equity	$ 515,905	$ 483,748

Corporate Contact:
AJ Jones II
Chief Corporate Affairs and Communications Officer
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:http://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-third-quarter-2020-financial-results-301162148.html

SOURCE Vanda Pharmaceuticals Inc.