



Vanda Pharmaceuticals Reports Third Quarter 2021 Financial Results

November 3, 2021

-- Q3 2021 total revenues were \$70.1 million, a 16% increase compared to Q3 2020

-- Total revenues for the first nine months of 2021 were \$200.7 million, an 11% increase compared to the first nine months of 2020

-- Enrollment of the Phase III clinical study of tradipitant in gastroparesis is complete and results are expected by the end of 2021

WASHINGTON, Nov. 3, 2021 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2021.

"Vanda is approaching another pivotal moment in its 18-year history with the upcoming completion of the Phase III study of tradipitant in gastroparesis and anticipated results by the end of this year. We believe that tradipitant has the potential to become the first new product in 40 years for the treatment of gastroparesis, a serious and debilitating disorder that severely impacts the lives of many people. Additionally, the launch of HETLIOZ[®] and HETLIOZ LQ[™] for nighttime sleep disturbances in people with Smith-Magenis Syndrome is progressing well as we are beginning our broad awareness campaign. Across all of our programs, patient access to innovative treatments remains a key goal of Vanda. We are currently working to address the escalating reimbursement delays for HETLIOZ[®], which are especially impacting Non-24 patients with light perception, and we are confident in our ability to drive positive outcomes for patients. I am proud of the Vanda team for continuing to advance Vanda's innovation objectives and creating value for patients and all of the company's stakeholders," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board.

Financial Highlights

Third Quarter of 2021

- Total net product sales from HETLIOZ[®] and Fanapt[®] were \$70.1 million in the third quarter of 2021, a 16% increase compared to \$60.3 million in the third quarter of 2020.
- HETLIOZ[®] net product sales were \$45.6 million in the third quarter of 2021, a 15% increase compared to \$39.6 million in the third quarter of 2020.
- Fanapt[®] net product sales were \$24.5 million in the third quarter of 2021, an 18% increase compared to \$20.7 million in the third quarter of 2020.
- Income before taxes was \$10.7 million in the third quarter of 2021 compared to \$8.4 million in the third quarter of 2020.

First Nine Months of 2021

- Total net product sales from HETLIOZ[®] and Fanapt[®] were \$200.7 million in the first nine months of 2021, an 11% increase compared to \$180.5 million in the first nine months of 2020.
- HETLIOZ[®] net product sales were \$129.5 million in the first nine months of 2021, an 11% increase compared to \$116.5 million in the first nine months of 2020.
- Fanapt[®] net product sales were \$71.2 million in the first nine months of 2021, an 11% increase compared to \$64.0 million in the first nine months of 2020.
- Income before taxes was \$33.8 million in the first nine months of 2021 compared to \$20.7 million in the first nine months of 2020.
- Cash, cash equivalents and marketable securities (Cash) was \$406.0 million as of September 30, 2021, representing an increase to Cash of \$57.4 million compared to September 30, 2020.

Net Product Sales

<i>(in thousands)</i>	Third Quarter			
	September 30	September 30	\$ Change	% Change
	2021	2020		
HETLIOZ [®] net product sales	\$ 45,615	\$ 39,618	\$ 5,997	15 %
Fanapt [®] net product sales	24,480	20,690	3,790	18 %
Total revenues	<u>\$ 70,095</u>	<u>\$ 60,308</u>	<u>\$ 9,787</u>	<u>16 %</u>

<i>(in thousands)</i>	First Nine Months			
	September 30	September 30	\$ Change	% Change
	2021	2020		
HETLIOZ [®] net product sales	\$ 129,467	\$ 116,515	\$ 12,952	11 %
Fanapt [®] net product sales	71,196	64,000	7,196	11 %

Total revenues	<u>\$ 200,663</u>	<u>\$ 180,515</u>	<u>\$ 20,148</u>	<u>11 %</u>
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Key Operational Highlights

Tradipitant

- Enrollment of the randomized portion of the Phase III clinical study of tradipitant in gastroparesis is complete. The randomized portion of the study is a 12-week study of approximately 200 patients with idiopathic or diabetic gastroparesis. Results are expected by the end of 2021. Enrollment of the open label portion of the study is ongoing with more than 250 patients enrolled.

HETLIOZ® (tasimelteon)

- Reimbursement challenges with HETLIOZ® prescriptions for patients with Non-24 have increased significantly. While Vanda is working to address these challenges and is confident in its ability to successfully navigate the current environment, Vanda is revising its HETLIOZ® net product sales guidance to \$170 to \$190 million from the prior HETLIOZ® net product sales guidance of \$180 to \$200 million.
- In December 2020, the 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 To date, more than 90 patients with SMS have been prescribed HETLIOZ® or HETLIOZ LQ™ and a broad awareness campaign is expected to begin during the fourth quarter of 2021.
- A Phase III clinical study of HETLIOZ® in delayed sleep phase disorder (DSPD) is currently enrolling patients. The study has a 28-day randomized evaluation period and plans to enroll approximately 300 patients. DSPD is likely the most [prevalent](#) circadian-rhythm sleep disorder, affecting approximately 1% of the population, and there is no FDA approved treatment at this time.²

Fanapt® (iloperidone)

- A Phase III clinical study of Fanapt® in acute bipolar mania disorder is currently enrolling. The study is a placebo controlled four-week evaluation of approximately 400 patients at sites in the U.S. and Europe.
- A repeat-dose clinical pharmacology study of the long acting injectable (LAI) formulation of Fanapt® is ongoing. A Phase III study of the LAI formulation for the treatment of acute schizophrenia is planned to follow the pharmacology study.
- Evaluation of P88, the active metabolite of iloperidone, has been initiated. P88 has the potential to improve the clinical profile of Fanapt® and create sustained, long-term value in the treatment of psychiatric disorders.

GAAP Financial Results

Income before taxes was \$10.7 million in the third quarter of 2021 compared to \$8.4 million in the third quarter of 2020. Net income was \$7.8 million in the third quarter of 2021 compared to net income of \$5.9 million in the third quarter of 2020. Diluted net income per share was \$0.14 in the third quarter of 2021 compared to diluted net income per share of \$0.11 in the third quarter of 2020.

Income before taxes was \$33.8 million in the first nine months of 2021 compared to \$20.7 million in the first nine months of 2020. Net income was \$26.1 million in the first nine months of 2021 compared to net income of \$15.1 million in the first nine months of 2020. Diluted net income per share was \$0.46 in the first nine months of 2021 compared to diluted net income per share of \$0.28 in the first nine months of 2020.

2021 Financial Guidance

Vanda is updating its 2021 financial guidance and expects to achieve the following financial objectives in 2021:

Full Year 2021 Financial Objectives	Revised Full Year 2021 Guidance	Prior Full Year 2021 Guidance
Total revenues	\$260 to \$290 million	\$270 to \$300 million
HETLIOZ® net product sales	\$170 to \$190 million	\$180 to \$200 million
Fanapt® net product sales	\$90 to \$100 million	\$90 to \$100 million
Year-end 2021 Cash	Greater than \$400 million	Greater than \$400 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, November 3, 2021, at 4:30 PM ET. During the call, Vanda's management will discuss the third 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 5961858. A replay of the call will be available on Wednesday, November 3, 2021, beginning at 7:30 PM ET and will be accessible until Wednesday, November 10, 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 5961858.

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>
2. P.J. Murphy, Delayed Sleep-Phase Type, *Encyclopedia of Sleep*, Academic Press, 2013, Pages 22-25, ISBN 9780123786111, <https://doi.org/10.1016/B978-0-12-378610-4.00268-0>

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 timelines for tradipitant and Fanapt[®] LAI, the therapeutic and commercial potential of tradipitant and P88, and Vanda's ability to address reimbursement challenges 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., Vanda's ability to complete the clinical development for tradipitant in the treatment of gastroparesis and Fanapt[®] LAI in the treatment of acute schizophrenia, Vanda's ability to obtain regulatory approval of tradipitant in the treatment of gastroparesis, the ability of P88 to improve the clinical profile of Fanapt[®], and Vanda's ability to improve patient access to 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 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		Nine Months Ended	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Revenues:				
HETLIOZ [®] net product sales	\$ 45,615	\$ 39,618	\$ 129,467	\$ 116,515
Fanapt [®] net product sales	24,480	20,690	71,196	64,000
Total revenues	70,095	60,308	200,663	180,515
Operating expenses:				
Cost of goods sold excluding amortization	6,797	5,898	19,393	16,952
Research and development	19,653	12,298	56,032	40,728
Selling, general and administrative	32,456	34,001	90,600	104,939
Intangible asset amortization	370	369	1,109	1,108
Total operating expenses	59,276	52,566	167,134	163,727
Income from operations	10,819	7,742	33,529	16,788
Other income (expense)	(97)	659	225	3,943
Income before income taxes	10,722	8,401	33,754	20,731
Provision for income taxes	2,951	2,454	7,680	5,584
Net income	<u>\$ 7,771</u>	<u>\$ 5,947</u>	<u>\$ 26,074</u>	<u>\$ 15,147</u>
Net income per share, basic	\$ 0.14	\$ 0.11	\$ 0.47	\$ 0.28
Net income per share, diluted	\$ 0.14	\$ 0.11	\$ 0.46	\$ 0.28
Weighted average shares outstanding, basic	55,668,156	54,666,128	55,467,528	54,325,832
Weighted average shares outstanding, diluted	57,040,736	55,209,032	56,818,295	55,054,772

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

	September 30 <u>2021</u>	December 31 <u>2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 50,522	\$ 61,031
Marketable securities	355,446	306,709
Accounts receivable, net	41,496	30,036
Inventory	902	1,280
Prepaid expenses and other current assets	<u>13,442</u>	<u>10,089</u>
Total current assets	461,808	409,145
Property and equipment, net	3,318	4,136
Operating lease right-of-use assets	9,580	10,459
Intangible assets, net	20,450	21,559
Deferred tax assets	76,105	81,516
Non-current inventory and other	<u>8,506</u>	<u>6,641</u>
Total assets	<u>\$ 579,767</u>	<u>\$ 533,456</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 31,820	\$ 31,509
Product revenue allowances	<u>40,177</u>	<u>34,427</u>
Total current liabilities	71,997	65,936
Operating lease non-current liabilities	10,457	11,497
Other non-current liabilities	<u>3,992</u>	<u>2,757</u>
Total liabilities	86,446	80,190
Stockholders' equity:		
Common stock	56	55
Additional paid-in capital	664,408	650,300
Accumulated other comprehensive income	111	239
Accumulated deficit	<u>(171,254)</u>	<u>(197,328)</u>
Total stockholders' equity	<u>493,321</u>	<u>453,266</u>
Total liabilities and stockholders' equity	<u>\$ 579,767</u>	<u>\$ 533,456</u>

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