

# Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results

- Full year 2021 total revenues grew to \$268.7 million, an 8% increase compared to 2020
- Full year 2022 total revenues expected to be between \$240 million and \$280 million
- End of year 2022 Cash expected to be greater than \$440 million

**WASHINGTON** – February 23, 2022 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: <u>VNDA</u>) today announced financial and operational results for the fourth quarter and full year ended December 31, 2021.

"We are proud of the progress we have made this past year with our existing products and in bringing HETLIOZ® to patients with Smith-Magenis Syndrome, leading to a strong financial performance, even in the face of extraordinary challenges," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "We advanced our clinical products pipeline with a number of programs in early and late-stage clinical development and we believe that our recently completed Phase III study of tradipitant in gastroparesis gets us closer to being able to provide a new treatment option for patients with this significant unmet medical need, despite the study not meeting its prespecified primary endpoint."

# **Financial Highlights**

#### Fourth Quarter of 2021

- Total net product sales from HETLIOZ® and Fanapt® were \$68.0 million in the fourth quarter of 2021, a 1% increase compared to \$67.7 million in the fourth quarter of 2020.
- HETLIOZ® net product sales were \$44.1 million in the fourth quarter of 2021 compared to \$44.2 million in the fourth quarter of 2020.
- Fanapt® net product sales were \$24.0 million in the fourth quarter of 2021, a 2% increase compared to \$23.5 million in the fourth quarter of 2020.
- Net income was \$7.1 million in the fourth quarter of 2021 compared to \$8.2 million in the fourth quarter of 2020.

#### Full Year 2021

- Total net product sales from HETLIOZ® and Fanapt® were \$268.7 million for the full year 2021, an 8% increase compared to \$248.2 million for the full year 2020.
- HETLIOZ® net product sales were \$173.5 million for the full year 2021, an 8% increase compared to \$160.7 million for the full year 2020.
- Fanapt® net product sales were \$95.1 million for the full year 2021, a 9% increase compared to \$87.5 million for the full year 2020.
- Net income was \$33.2 million for the full year 2021 compared to \$23.3 million for the full year 2020.
- Cash, cash equivalents and marketable securities (Cash) was \$432.8 million as of December 31, 2021, representing an increase to Cash of \$65.1 million compared to December 31, 2020.

#### **Net Product Sales**

	Fourth Quarter						
(in thousands)	Dec	cember 31 2021	De	cember 31 2020		\$ Change	% Change
HETLIOZ® net product sales	\$	44,069	\$	44,171	\$	(102)	— %
Fanapt® net product sales		23,950		23,482		468	2 %
Total revenues	\$	68,019	\$	67,653	\$	366	1 %

	Full Year						
(in thousands)	D	ecember 31 2021	D	December 31 2020		\$ Change	% Change
HETLIOZ® net product sales	\$	173,536	\$	160,686	\$	12,850	8 %
Fanapt® net product sales		95,146		87,482		7,664	9 %
Total revenues	\$	268,682	\$	248,168	\$	20,514	8 %

## **Key Operational Highlights**

## HETLIOZ® (tasimelteon)

- In January 2022, Vanda announced it has settled its HETLIOZ® patent litigation against MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited. The litigation remains pending against the other defendants.¹
- In November 2021, a HETLIOZ® patient filed a federal lawsuit challenging the unlawfulness of Colorado Medicaid's prior authorization criteria, which limited HETLIOZ® coverage to totally blind patients. In response to the lawsuit, Colorado changed its criteria to cover HETLIOZ® for all Non-24 patients and to no longer restrict HETLIOZ® coverage on the basis of vision status. Since then, 10 additional states have revised their criteria to eliminate the restriction of HETLIOZ® coverage to totally blind patients.

#### **Tradipitant**

 In February 2022, Vanda reported the results from the Phase III study (VP-VLY-686-3301) of tradipitant in gastroparesis. The study did not meet its prespecified primary endpoint, but significant treatment effects were observed when adjusting for confounding factors. Vanda plans to complete the analysis of the data of this study and prepare for submission to regulatory authorities and scientific journals.<sup>2</sup>

### Fanapt® (iloperidone)

• A Phase III clinical study of Fanapt<sup>®</sup> in acute manic episodes in patients with bipolar disorder is now more than 50% enrolled and expected to complete enrollment by the end of 2022.

#### **GAAP Financial Results**

Net income was \$7.1 million in the fourth quarter of 2021 compared to net income of \$8.2 million in the fourth quarter of 2020. Diluted net income per share was \$0.12 in the fourth quarter of 2021 compared to diluted net income per share of \$0.15 in the fourth quarter of 2020.

Net income was \$33.2 million for the full year 2021 compared to net income of \$23.3 million for the full year 2020. Diluted net income per share was \$0.58 for the full year 2021 compared to diluted net income per share of \$0.42 for the full year 2020.

#### 2022 Financial Guidance

Vanda expects to achieve the following financial objectives in 2022:

Full Year 2022 Financial Objectives	Full Year 2022 Guidance
Total revenues	\$240 to \$280 million
HETLIOZ® net product sales	\$150 to \$180 million
Fanapt® net product sales	\$90 to \$100 million
Year-end 2022 Cash	Greater than \$440 million

#### **Conference Call**

Vanda has scheduled a conference call for today, Wednesday, February 23, 2022, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2021 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode number 5373895. A replay of the call will be available on Wednesday, February 23, 2022, beginning at 7:30 PM ET and will be accessible until Wednesday, March 2, 2022 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 5373895.

The conference call will be broadcast simultaneously on Vanda's website, <a href="www.vandapharma.com">www.vandapharma.com</a>. 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 Settles HETLIOZ® Patent Litigation with MSN" issued on January 14, 2022. <a href="https://vandapharmaceuticalsinc.gcs-web.com/node/14766/pdf">https://vandapharmaceuticalsinc.gcs-web.com/node/14766/pdf</a>
- 2. Refer to Company press release titled "Vanda Pharmaceuticals Reports Results from the Phase III Study of Tradipitant in Gastroparesis" issued on February 4, 2022. https://vandapharmaceuticalsinc.gcs-web.com/node/14786/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 <a href="www.vandapharma.com">www.vandapharma.com</a> 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 "2022 Financial Guidance" above and statements regarding Vanda's plans for further analysis of the data from the tradipitant Phase III study and publication of study results and continued pursuit of regulatory approval of tradipitant for the treatment of gastroparesis and the clinical development timelines for Fanapt<sup>®</sup> 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 the strength of its business in the U.S., Vanda's ability to complete the clinical development of, and obtain regulatory approval for, tradipitant in the treatment of gastroparesis and Vanda's ability to complete enrollment of the Phase III clinical study of Fanapt® in bipolar disorder. 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. Forwardlooking 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 Mo	Ended		Twelve Months Ended				
	 December 31 2021		December 31 2020		December 31 2021		December 31 2020	
Revenues:								
HETLIOZ® net product sales	\$ 44,069	\$	44,171	\$	173,536	\$	160,686	
Fanapt® net product sales	23,950		23,482		95,146		87,482	
Total revenues	68,019		67,653		268,682		248,168	
Operating expenses:								
Cost of goods sold excluding amortization	6,236		6,412		25,629		23,364	
Research and development	19,331		14,849		75,363		55,577	
Selling, general and administrative	33,447		35,571		124,047		140,510	
Intangible asset amortization	369		370		1,478		1,478	
Total operating expenses	59,383		57,202		226,517		220,929	
Income from operations	 8,636		10,451		42,165		27,239	
Other income (expense)	(26)		473		199		4,416	
Income before income taxes	8,610		10,924		42,364		31,655	
Provision for income taxes	 1,532		2,734		9,212		8,318	
Net income	\$ 7,078	\$	8,190	\$	33,152	\$	23,337	
Net income per share, basic	\$ 0.13	\$	0.15	\$	0.60	\$	0.43	
Net income per share, diluted	\$ 0.12	\$	0.15	\$	0.58	\$	0.42	
Weighted average shares outstanding, basic	55,787,252		54,731,042		55,548,122		54,427,683	
Weighted average shares outstanding, diluted	57,229,805		55,596,697		56,921,836		55,190,802	

# VANDA PHARMACEUTICALS INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands) (unaudited)

	December 31 2021		December 31 2020
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 52,07	1 \$	61,031
Marketable securities	380,74	2	306,709
Accounts receivable, net	32,46	7	30,036
Inventory	1,02	5	1,280
Prepaid expenses and other current assets	11,99	5	10,089
Total current assets	478,30	1	409,145
Property and equipment, net	3,11	3	4,136
Operating lease right-of-use assets	9,27	2	10,459
Intangible assets, net	20,08	1	21,559
Deferred tax assets	74,87	3	81,516
Non-current inventory and other	8,14	7	6,641
Total assets	\$ 593,79	2 \$	533,456
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable and accrued liabilities	\$ 34,43	8 \$	31,509
Product revenue allowances	39,98	1	34,427
Total current liabilities	74,41	)	65,936
Operating lease non-current liabilities	10,05	5	11,497
Other non-current liabilities	4,39	)	2,757
Total liabilities	88,86	4	80,190
Stockholders' equity:			
Common stock	5	5	55
Additional paid-in capital	669,22	3	650,300
Accumulated other comprehensive income (loss)	(17)	5)	239
Accumulated deficit	(164,17	5)	(197,328)
Total stockholders' equity	504,92	3	453,266
Total liabilities and stockholders' equity	\$ 593,79	2 \$	533,456

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