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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): February 23, 2022**

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**VANDA PHARMACEUTICALS INC.**  
(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of incorporation)

**001-34186**  
(Commission File No.)

**03-0491827**  
(IRS Employer Identification No.)

**2200 Pennsylvania Avenue NW  
Suite 300E  
Washington, DC 20037**  
(Address of principal executive offices and zip code)

**Registrant's telephone number, including area code: (202) 734-3400**

**Not Applicable**  
(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
<b>Common Stock, par value \$0.001 per share</b>	<b>VNDA</b>	<b>The Nasdaq Global Market</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operations and Financial Condition.**

On February 23, 2022, Vanda Pharmaceuticals Inc. (“Vanda”) issued a press release and is holding a conference call regarding its results of operations and financial condition for the quarter and full year ended December 31, 2021. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are “forward-looking statements” under the securities laws, including, but not limited to, Vanda’s financial guidance for 2022, and statements regarding Vanda’s commercial products, plans and opportunities, as well as statements about Vanda’s products in development and the related clinical development and regulatory timelines and commercial potential for such products. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “project,” “target,” “goal,” “likely,” “will,” “would,” and “could,” or the negative of these terms and similar expressions or words, identify 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. and Vanda’s ability to complete the clinical development of, and obtain regulatory approval for, tradipitant in the treatment of gastroparesis. Therefore, no assurance can be given 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. Forward-looking statements made during the call 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](http://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. The information contained in this Current Report on Form 8-K is intended to be considered in the context of Vanda’s filings with the SEC and other public announcements that Vanda makes, by press release or otherwise, from time to time. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information conveyed on the conference call will be provided only as of the date of the call, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the call after the date thereof, whether as a result of new information, future events or otherwise, except as required by law.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release of Vanda Pharmaceuticals Inc. dated February 23, 2022.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 23, 2022

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel and Secretary



## 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 /PRNewswire/ – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) 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<sup>®</sup> 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<sup>®</sup> and Fanapt<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Fanapt<sup>®</sup> were \$268.7 million for the full year 2021, an 8% increase compared to \$248.2 million for the full year 2020.
- HETLIOZ<sup>®</sup> 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<sup>®</sup> 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

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

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

## Key Operational Highlights

### HETLIOZ<sup>®</sup> (tasimelteon)

- In January 2022, Vanda announced it has settled its HETLIOZ<sup>®</sup> patent litigation against MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited. The litigation remains pending against the other defendants.<sup>1</sup>
- In November 2021, a HETLIOZ<sup>®</sup> patient filed a federal lawsuit challenging the unlawfulness of Colorado Medicaid's prior authorization criteria, which limited HETLIOZ<sup>®</sup> coverage to totally blind patients. In response to the lawsuit, Colorado changed its criteria to cover HETLIOZ<sup>®</sup> for all Non-24 patients and to no longer restrict HETLIOZ<sup>®</sup> coverage on the basis of vision status. Since then, 10 additional states have revised their criteria to eliminate the restriction of HETLIOZ<sup>®</sup> 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<sup>®</sup> (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 <sup>®</sup> net product sales	\$150 to \$180 million
Fanapt <sup>®</sup> 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, [www.vandapharma.com](http://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 Settles HETLIOZ<sup>®</sup> Patent Litigation with MSN" issued on January 14, 2022. <https://vandapharmaceuticalsinc.gcs-web.com/node/14766/pdf>
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 [www.vandapharma.com](http://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 "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<sup>®</sup> 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. 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](http://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		Twelve Months Ended	
	December 31 2021	December 31 2020	December 31 2021	December 31 2020
<b>Revenues:</b>				
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
<b>Operating expenses:</b>				
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	<u>\$ 7,078</u>	<u>\$ 8,190</u>	<u>\$ 33,152</u>	<u>\$ 23,337</u>
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
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 52,071	\$ 61,031
Marketable securities	380,742	306,709
Accounts receivable, net	32,467	30,036
Inventory	1,025	1,280
Prepaid expenses and other current assets	11,996	10,089
Total current assets	478,301	409,145
Property and equipment, net	3,113	4,136
Operating lease right-of-use assets	9,272	10,459
Intangible assets, net	20,081	21,559
Deferred tax assets	74,878	81,516
Non-current inventory and other	8,147	6,641
Total assets	\$ 593,792	\$ 533,456
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 34,438	\$ 31,509
Product revenue allowances	39,981	34,427
Total current liabilities	74,419	65,936
Operating lease non-current liabilities	10,055	11,497
Other non-current liabilities	4,390	2,757
Total liabilities	88,864	80,190
Stockholders' equity:		
Common stock	56	55
Additional paid-in capital	669,223	650,300
Accumulated other comprehensive income (loss)	(175)	239
Accumulated deficit	(164,176)	(197,328)
Total stockholders' equity	504,928	453,266
Total liabilities and stockholders' equity	\$ 593,792	\$ 533,456

Corporate Contact:

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