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

FORM 8-K

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 10, 2021

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

001-34186	Delaware	03-0491827
(Commission File No.)	(State or other jurisdiction of incorporation)	(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)

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:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**VNDA**	**The Nasdaq Global Market**

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On February 10, 2021, 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, 2020. 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 2020. 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 its ability to continue to grow its business in the U.S.; the ability of Vanda's third-party manufacturer to timely provide Vanda with a supply of the HETLIOZ LQ™ oral suspension, and Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis and COVID-19 pneumonia, HETLIOZ® in the treatment of delayed sleep phase disorder and autism spectrum disorder, Fanapt® long acting injectable in the treatment of schizophrenia, and Fanapt® in the treatment of Parkinson's disease psychosis. 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. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved. Forward-looking statements made during this 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, 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. 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, 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

Exhibit No.	Description
99.1	Press release of Vanda Pharmaceuticals Inc. dated February 10, 2021.
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 10, 2021

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams
Name: Timothy Williams
Title: Senior Vice President, General Counsel and Secretary

Exhibit 99.1

Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results

- *Q4 2020 total revenues grew to $67.7 million, an 11% increase compared to Q4 2019*
- *Full year 2020 total revenues grew to $248.2 million, a 9% increase compared to 2019*
- *Full year 2021 total revenues expected to be between $270 million and $300 million, an increase of approximately 15% compared to 2020*
- *End of year 2021 Cash expected to be greater than $400 million*

WASHINGTON – February 10, 2021 /PRNewswire/ – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the fourth quarter and full year ended December 31, 2020.

"I am very proud of the significant accomplishments we realized during this challenging year," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda. "As we look forward to the new year, it is worth noting some of our significant accomplishments from 2020: Vanda achieved record commercial revenue despite extraordinary difficulty in the field, which we believe is a testament to the value our products bring to patients; HETLIOZ® received FDA approval for nighttime sleep disturbances in patients with Smith-Magenis Syndrome; our tradipitant gastroparesis Phase III study continued recruitment; the FDA approved individual Expanded Access to tradipitant for multiple gastroparesis patients; we launched the tradipitant study for COVID-19 pneumonia; the FDA approved the Investigational New Drug application for VSJ-110 in allergic conjunctivitis; the United States Supreme Court affirmed the patent ruling on Fanapt®; and our research and development efforts advanced the clinical programs for our commercial assets as well as those in our pipeline. We look forward to another great year of accomplishments, including further revenue growth, the commercial launch of HETLIOZ® in patients with Smith-Magenis Syndrome, and the results of the tradipitant Phase III study in gastroparesis, to highlight a few."

Key Financial and Corporate Highlights

Fourth Quarter of 2020

- Total net product sales from HETLIOZ® and Fanapt® were $67.7 million in the fourth quarter of 2020, an 11% increase compared to $60.9 million in the fourth quarter of 2019.
- HETLIOZ® net product sales were $44.2 million in the fourth quarter of 2020, a 14% increase compared to $38.6 million in the fourth quarter of 2019.
- Fanapt® net product sales were $23.5 million in the fourth quarter of 2020, a 5% increase compared to $22.3 million in the fourth quarter of 2019.
- Income before taxes was $10.9 million in the fourth quarter of 2020 compared to $5.8 million in the fourth quarter of 2019.

Full Year 2020

- Total net product sales from HETLIOZ® and Fanapt® were $248.2 million for the full year 2020, a 9% increase compared to $227.2 million for the full year 2019.
- HETLIOZ® net product sales were $160.7 million for the full year 2020, a 12% increase compared to $143.0 million for the full year 2019.
- Fanapt® net product sales were $87.5 million for the full year 2020, a 4% increase compared to $84.2 million for the full year 2019.
- Income before taxes was $31.7 million for the full year 2020 compared to $29.0 million for the full year 2019.

- Cash, cash equivalents and marketable securities (Cash) was $367.7 million as of December 31, 2020, representing an increase to Cash of $55.6 million compared to December 31, 2019.

Key Product and Pipeline Highlights

Products

Vanda is encouraged by the strength of its commercial performance during the fourth quarter of 2020. Vanda continues to implement marketing and sales strategies aimed at supporting 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 in 2020. Vanda is continuing its activities to support and facilitate the treatment of individuals in the U.S. living with Smith-Magenis Syndrome (SMS), and is committed to its awareness campaign and the support of patients suffering with Non-24-Hour Sleep-Wake Disorder.

Pipeline

Tradipitant

- The gastroparesis Phase III clinical study (VP-VLY-686-3301) is ongoing. The study has a target enrollment of 200 randomized patients and is expected to complete enrollment in the first half of 2021, with a New Drug Application (NDA) filing projected in the second half of 2021.
- The COVID-19 pneumonia Phase III clinical study (ODYSSEY VLY-686-3501) is ongoing.

HETLIOZ® (tasimelteon)

- In December 2020, the U.S. Food and Drug Administration (FDA) approved HETLIOZ® capsule and liquid formulations for the treatment of adults and children, respectively, with nighttime sleep disturbances in SMS.[1] HETLIOZ® capsules, for adults with SMS, were immediately available after approval and the HETLIOZ LQ™ liquid formulation, for children with SMS, is expected to be available in the first quarter of 2021. SMS is estimated to affect 1/15,000-25,000 births in the U.S.[2] HETLIOZ® is the first and only FDA approved medication for patients with SMS.
- A Phase III clinical study for HETLIOZ® in delayed sleep phase disorder (DSPD) is expected to be initiated in the first quarter of 2021.
- A clinical development program for HETLIOZ® in autism spectrum disorder (ASD) is expected to be initiated in the first quarter of 2021.

Fanapt® (iloperidone)

- Development of the long acting injectable (LAI) formulation of Fanapt® is ongoing.
- A clinical program for Fanapt® in Parkinson's disease psychosis (PDP) is expected to begin in the first quarter of 2021.

GAAP Financial Results

Income before taxes was $10.9 million in the fourth quarter of 2020 compared to $5.8 million in the fourth quarter of 2019. Net income was $8.2 million in the fourth quarter of 2020 compared to net income of $4.2 million in the fourth quarter of 2019. Diluted net income per share was $0.15 in the fourth quarter of 2020 compared to diluted net income per share of $0.08 in the fourth quarter of 2019.

Income before taxes was $31.7 million for the full year 2020 compared to $29.0 million for the full year 2019. Net income was $23.3 million for the full year 2020 compared to net income of $115.6 million for the full year 2019. The full year 2019 net income of $115.6 million and the 2019 income tax benefit of $86.5 million include the favorable impact of the release of Vanda’s deferred tax asset valuation allowance.

Diluted net income per share was $0.42 for the full year 2020 compared to diluted net income per share of $2.11 for the full year 2019.

2021 Financial Guidance

Vanda expects to achieve the following financial objectives in 2021**:**

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

Conference Call

Vanda has scheduled a conference call for today, Wednesday, February 10, 2021, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 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 3557867. A replay of the call will be available on Wednesday, February 10, 2021, beginning at 7:30 PM ET and will be accessible until Wednesday, February 17, 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 3557867.

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. Orphanet ORPHA number 819.

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 Vanda's revenue expectations for 2021, the commercial launch of HETLIOZ® for the treatment of patients with SMS, Vanda's marketing and sales strategies, the expected availability of the HETLIOZ LQ™ liquid formulation and the clinical development and regulatory timelines for tradipitant, HETLIOZ® and Fanapt®, 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., the ability of Vanda's third-party manufacturer to timely provide Vanda with a supply of the HETLIOZ LQ™ liquid formulation, and Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis and COVID-19 pneumonia, HETLIOZ® in the treatment of DSPD and ASD, Fanapt® LAI in the treatment of schizophrenia, and Fanapt® in the treatment of PDP. 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. 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		Twelve Months Ended	
	December 31 2020	December 31 2019	December 31 2020	December 31 2019
Revenues:				
HETLIOZ® net product sales	$ 44,171	$ 38,599	$ 160,686	$ 142,980
Fanapt® net product sales	23,482	22,331	87,482	84,208
Total revenues	67,653	60,930	248,168	227,188
Operating expenses:				
Cost of goods sold excluding amortization	6,412	6,225	23,364	24,488
Research and development	14,849	13,074	55,577	48,649
Selling, general and administrative	35,571	37,018	140,510	129,736
Intangible asset amortization	370	370	1,478	1,505
Total operating expenses	57,202	56,687	220,929	204,378
Income from operations	10,451	4,243	27,239	22,810
Other income	473	1,567	4,416	6,218
Income before income taxes	10,924	5,810	31,655	29,028
Provision (benefit) for income taxes	2,734	1,594	8,318	(86,525)
Net income	$ 8,190	$ 4,216	$ 23,337	$ 115,553
Net income per share, basic	$ 0.15	$ 0.08	$ 0.43	$ 2.17
Net income per share, diluted	$ 0.15	$ 0.08	$ 0.42	$ 2.11
Weighted average shares outstanding, basic	54,731,042	53,389,950	54,427,683	53,137,562
Weighted average shares outstanding, diluted	55,596,697	54,973,952	55,190,802	54,847,060

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

	December 31 2020	December 31 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,031	$ 45,072
Marketable securities	306,709	267,057
Accounts receivable, net	30,036	26,367
Inventory	1,280	1,140
Prepaid expenses and other current assets	10,089	14,500
Total current assets	409,145	354,136
Property and equipment, net	4,136	3,864
Operating lease right-of-use assets	10,459	11,180
Intangible assets, net	21,559	23,037
Deferred tax assets	81,516	87,680
Non-current inventory and other	6,641	3,851
Total assets	$ 533,456	$ 483,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 31,509	$ 27,590
Product revenue allowances	34,427	31,915
Total current liabilities	65,936	59,505
Operating lease non-current liabilities	11,497	12,455
Other non-current liabilities	2,757	843
Total liabilities	80,190	72,803
Stockholders' equity:		
Common stock	55	54
Additional paid-in capital	650,300	631,307
Accumulated other comprehensive income	239	249
Accumulated deficit	(197,328)	(220,665)
Total stockholders' equity	453,266	410,945
Total liabilities and stockholders' equity	$ 533,456	$ 483,748

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