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): November 3, 2021

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

Delaware	**001-34186**	**03-0491827**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(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 November 3, 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 ended September 30, 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 2021, 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 its ability to continue to grow its business in the U.S., Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis, the prevalence of gastroparesis, Vanda's ability to successfully commercialize tradipitant and Vanda's ability to complete the clinical development and obtain regulatory approval for its other products in development. 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.

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 November 3, 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: November 3, 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 Third Quarter 2021 Financial Results

- *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 – November 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

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

	First Nine Months			
(in thousands)	September 30 2021	September 30 2020	$ Change	% Change
HETLIOZ® net product sales	$ 129,467	$ 116,515	$ 12,952	11 %
Fanapt® net product sales	71,196	64,000	7,196	11 %
Total revenues	$ 200,663	$ 180,515	$ 20,148	11 %

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	$ 7,771	$ 5,947	$ 26,074	$ 15,147
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 2021	December 31 2020
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	13,442	10,089
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	8,506	6,641
Total assets	$ 579,767	$ 533,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 31,820	$ 31,509
Product revenue allowances	40,177	34,427
Total current liabilities	71,997	65,936
Operating lease non-current liabilities	10,457	11,497
Other non-current liabilities	3,992	2,757
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	(171,254)	(197,328)
Total stockholders' equity	493,321	453,266
Total liabilities and stockholders' equity	$ 579,767	$ 533,456

Corporate Contact:

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