
**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): July 28, 2021

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

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)

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>
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 July 28, 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 June 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Vanda Pharmaceuticals Inc. dated July 28, 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: July 28, 2021

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel and Secretary



Vanda Pharmaceuticals Reports Second Quarter 2021 Financial Results

- Q2 2021 total revenues were \$67.9 million, a 9% increase compared to Q2 2020
- Total revenues for the first six months of 2021 were \$130.6 million, a 9% increase compared to the first six months of 2020
- Results from Phase III clinical study of tradipitant in gastroparesis are expected by the end of 2021

WASHINGTON – July 28, 2021 /PRNewswire/ – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2021.

“Vanda had another outstanding quarter of commercial revenue growth as we resumed activity across a number of our clinical programs. Our tradipitant in gastroparesis program is nearing completion, bringing us closer to a much-needed new treatment option for patients with gastroparesis and a potentially transformational commercial opportunity for Vanda,” said Mihael H. Polymeropoulos, M.D., Vanda’s President, CEO and Chairman of the Board.

Financial Highlights

Second Quarter of 2021

- Total net product sales from HETLIOZ® and Fanapt® were \$67.9 million in the second quarter of 2021, a 9% increase compared to \$62.2 million in the second quarter of 2020.
- HETLIOZ® net product sales were \$44.5 million in the second quarter of 2021, a 7% increase compared to \$41.6 million in the second quarter of 2020.
- Fanapt® net product sales were \$23.4 million in the second quarter of 2021, a 13% increase compared to \$20.6 million in the second quarter of 2020.
- Income before taxes was \$12.6 million in the second quarter of 2021 compared to \$11.1 million in the second quarter of 2020.

First Six Months of 2021

- Total net product sales from HETLIOZ® and Fanapt® were \$130.6 million in the first six months of 2021, a 9% increase compared to \$120.2 million in the first six months of 2020.
- HETLIOZ® net product sales were \$83.9 million in the first six months of 2021, a 9% increase compared to \$76.9 million in the first six months of 2020.
- Fanapt® net product sales were \$46.7 million in the first six months of 2021, an 8% increase compared to \$43.3 million in the first six months of 2020.
- Income before taxes was \$23.0 million in the first six months of 2021 compared to \$12.3 million in the first six months of 2020.
- Cash, cash equivalents and marketable securities (Cash) was \$396.5 million as of June 30, 2021, representing an increase to Cash of \$56.6 million compared to June 30, 2020.

Key Operational Highlights

Tradipitant

- The Phase III clinical study of tradipitant in gastroparesis is nearing completion with 95% of the target 200 patients already enrolled. Results are expected by the end of 2021.

HETLIOZ® (tasimelteon)

- A Phase III clinical study of HETLIOZ® in delayed sleep phase disorder (DSPD) is currently enrolling patients.

Fanapt® (iloperidone)

- A Phase III clinical study of Fanapt® in bipolar disorder is currently enrolling patients. A clinical pharmacology study of the long acting injectable (LAI) formulation of Fanapt® is ongoing.

Key Publications

- The article “Tasimelteon safely and effectively improves sleep in Smith–Magenis syndrome: a double-blind randomized trial followed by an open-label extension” was published in July 2021 in *Genetics in Medicine*.¹

GAAP Financial Results

Income before taxes was \$12.6 million in the second quarter of 2021 compared to \$11.1 million in the second quarter of 2020. Net income was \$9.7 million in the second quarter of 2021 compared to net income of \$8.7 million in the second quarter of 2020. Diluted net income per share was \$0.17 in the second quarter of 2021 compared to diluted net income per share of \$0.16 in the second quarter of 2020.

Income before taxes was \$23.0 million in the first six months of 2021 compared to \$12.3 million in the first six months of 2020. Net income was \$18.3 million in the first six months of 2021 compared to net income of \$9.2 million in the first six months of 2020. Diluted net income per share was \$0.32 in the first six months of 2021 compared to diluted net income per share of \$0.17 in the first six months of 2020.

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, July 28, 2021, at 4:30 PM ET. During the call, Vanda’s management will discuss the second 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 5298904. A replay of the call will be available on Wednesday, July 28, 2021, beginning at 7:30 PM ET and will be accessible until Wednesday, August 4, 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 5298904.

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. Polymeropoulos, C.M., Brooks, J., Czeisler, E.L., Fisher, M.A., Gibson, M.M., Kite, K., Smieszek, S.P., Xiao, C., Elsea, S.H., Birznieks, G., Polymeropoulos, M.H. (2021). Tasimelteon safely and effectively improves sleep in Smith–Magenis syndrome: a double-blind randomized trial followed by an open-label extension. *Genetics in Medicine*. <https://doi.org/10.1038/s41436-021-01282-y>

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 and regulatory timelines and commercial potential for tradipitant 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 and obtain regulatory approval for tradipitant in the treatment of gastroparesis, the prevalence of gastroparesis and Vanda’s ability to successfully commercialize tradipitant. 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		Six Months Ended	
	June 30 2021	June 30 2020	June 30 2021	June 30 2020
Revenues:				
HETLIOZ® net product sales	\$ 44,509	\$ 41,561	\$ 83,852	\$ 76,897
Fanapt® net product sales	23,390	20,646	46,716	43,310
Total revenues	67,899	62,207	130,568	120,207
Operating expenses:				
Cost of goods sold excluding amortization	6,566	5,847	12,596	11,054
Research and development	20,248	12,903	36,379	28,430
Selling, general and administrative	28,347	33,917	58,144	70,938
Intangible asset amortization	369	369	739	739
Total operating expenses	55,530	53,036	107,858	111,161
Income from operations	12,369	9,171	22,710	9,046
Other income	235	1,918	322	3,284
Income before income taxes	12,604	11,089	23,032	12,330
Provision for income taxes	2,951	2,375	4,729	3,130
Net income	<u>\$ 9,653</u>	<u>\$ 8,714</u>	<u>\$ 18,303</u>	<u>\$ 9,200</u>
Net income per share, basic	\$ 0.17	\$ 0.16	\$ 0.33	\$ 0.17
Net income per share, diluted	\$ 0.17	\$ 0.16	\$ 0.32	\$ 0.17
Weighted average shares outstanding, basic	55,582,916	54,501,308	55,365,558	54,153,812
Weighted average shares outstanding, diluted	56,903,340	55,081,397	56,705,419	54,975,771

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

	June 30 2021	December 31 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,242	\$ 61,031
Marketable securities	339,251	306,709
Accounts receivable, net	37,090	30,036
Inventory	1,055	1,280
Prepaid expenses and other current assets	12,014	10,089
Total current assets	446,652	409,145
Property and equipment, net	3,631	4,136
Operating lease right-of-use assets	9,898	10,459
Intangible assets, net	20,820	21,559
Deferred tax assets	78,641	81,516
Non-current inventory and other	8,003	6,641
Total assets	\$ 567,645	\$ 533,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 31,788	\$ 31,509
Product revenue allowances	40,201	34,427
Total current liabilities	71,989	65,936
Operating lease non-current liabilities	10,740	11,497
Other non-current liabilities	3,696	2,757
Total liabilities	86,425	80,190
Stockholders' equity:		
Common stock	56	55
Additional paid-in capital	660,086	650,300
Accumulated other comprehensive income	103	239
Accumulated deficit	(179,025)	(197,328)
Total stockholders' equity	481,220	453,266
Total liabilities and stockholders' equity	\$ 567,645	\$ 533,456

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