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): August 5, 2020

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 August 5, 2020, 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, 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 that involve risks, changes in circumstances, assumptions 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 minimize the disruption caused by, and maintain business continuity during, the global COVID-19 pandemic and related market volatility; the duration and severity of the global COVID-19 pandemic, including prevailing economic conditions and general uncertainties relating thereto that may be unknown and unforeseeable; Vanda's ability to enroll patients in and complete its gastroparesis, motion sickness and ODYSSEY studies; Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis, motion sickness, atopic dermatitis and COVID-19 Acute Respiratory Distress Syndrome; Vanda's ability to successfully resume the clinical programs that are currently on hold and the U.S. Food and Drug Administration's ability to complete its review of the HETLIOZ® applications for the treatment of Smith-Magenis Syndrome ("SMS") on time and make the determination that HETLIOZ® is safe and effective in the treatment of SMS in adults and children. There can be no assurance 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 the conference 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 August 5, 2020.
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: August 5, 2020

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel and Secretary

Exhibit 99.1

Vanda Pharmaceuticals Reports Second Quarter 2020 Financial Results

- *Q2 2020 Total net product sales reached a new record of $62.2 million, a 7% increase as compared to Q1 2020*
- *Q2 2020 HETLIOZ® net product sales reached a new record of $41.6 million, an 18% increase as compared to Q1 2020*
- *The HETLIOZ® SMS marketing authorization applications were accepted for priority review by the FDA*

WASHINGTON – August 5, 2020 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2020.

"We are very proud of the achievements of our team, especially the record commercial performance, even in the face of the challenges presented by the pandemic. We are also very excited with the progress of the HETLIOZ® SMS applications as we get closer to providing a therapeutic solution to patients with SMS," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO.

Key Financial and Corporate Highlights

- Total revenues from HETLIOZ® and Fanapt® were $62.2 million in the second quarter of 2020, a 5% increase compared to $59.1 million in the second quarter of 2019.
- HETLIOZ® net product sales were $41.6 million in the second quarter of 2020, a 10% increase compared to $37.8 million in the second quarter of 2019.
- Fanapt® net product sales were $20.6 million in the second quarter of 2020, a 3% decrease compared to $21.2 million in the second quarter of 2019.
- Cash, cash equivalents and marketable securities (Cash) were $339.8 million as of June 30, 2020, representing an increase to Cash of $47.2 million compared to June 30, 2019.
- Net income was $8.7 million in the second quarter of 2020, compared to net income of $11.5 million in the second quarter of 2019.

Key Product and Pipeline Highlights

Products

Vanda is encouraged by its record commercial performance during the second quarter of 2020. Vanda continues to implement marketing and sales strategies aimed at supporting continued growth and minimizing the impact of disruptions caused by the COVID-19 pandemic, including the launch of a Fanapt® for schizophrenia direct-to-consumer campaign at the end of the second quarter of 2020.

Pipeline

The COVID-19 pandemic has impacted clinical research globally, including Vanda's previously reported clinical trials. The tradipitant gastroparesis and motion sickness programs have resumed, while recruitment for the tradipitant atopic dermatitis program, as well as the HETLIOZ® delayed sleep phase disorder study and Fanapt® bipolar disorder and long acting injectable studies, is currently on hold.

Tradipitant

- An Individual Patient Expanded Access protocol (VP-VLY-686-3303) for tradipitant in gastroparesis was approved by the U.S. Food and Drug Administration (FDA) and the patient was enrolled in July 2020. Under this protocol, this patient will receive tradipitant treatment for a period of up to six months, which may be extended upon review by the FDA.

- The gastroparesis Phase III clinical study (VP-VLY-686-3301) resumed recruitment. Enrollment in this 200-person study is expected to be completed in the first half of 2021 with a New Drug Application (NDA) filing projected for later that year.
- The protocol for the pivotal Phase III motion sickness study was discussed with the FDA at the end of Phase II meeting, and the FDA agrees with the adequacy of the program design to support an application. Preparations for this study have begun with the boat trip portion of the study expected to commence as soon as local restrictions are lifted.
- Patient enrollment in the Phase III clinical study (ODYSSEY VLY-686-3501) of tradipitant in COVID-19 Acute Respiratory Distress Syndrome (ARDS) is ongoing and an interim analysis will be conducted to determine next steps.

HETLIOZ® (tasimelteon)

- The Smith-Magenis Syndrome (SMS) marketing authorization applications were accepted by the FDA for priority review with a Prescription Drug User Fee Act (PDUFA-VI) target action date of December 1, 2020.[1]
- The FDA appeals process related to the sNDA for HETLIOZ® for the treatment of jet lag disorder is ongoing.

Key Publications

- The article “Efficacy and Safety of Tradipitant in Patients with Diabetic and Idiopathic Gastroparesis in a Randomized, Placebo-Controlled Trial” was accepted for publication in the July 2020 issue of Gastroenterology.[2]
- The article "Efficacy of Tasimelteon (HETLIOZ®) in the Treatment of Jet Lag Disorder Evaluated in an 8-h Phase Advance Model; a Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial” was published in the July 2020 issue of Frontiers in Neurology.[3]

GAAP Financial Results

Net income was $8.7 million in the second quarter of 2020, compared to net income of $11.5 million in the second quarter of 2019. Diluted net income per share was $0.16 in the second quarter of 2020, compared to diluted net income per share of $0.21 in the second quarter of 2019.

2020 Financial Guidance

Vanda will continue to assess the impact of the evolving pandemic on its business and operations and will provide future updates to its financial guidance as necessary. The financial guidance previously communicated by Vanda is shown below. In addition, Vanda provides an update to Year-end 2020 Cash.

Full Year 2020 Financial Objectives	Full Year 2020 Guidance
Total revenues	$240 to $260 million
HETLIOZ® net product sales	$155 to $165 million
Fanapt® net product sales	$85 to $95 million
Year-end 2020 Cash	Greater than $340 million as compared to prior guidance of greater than $320 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, August 5, 2020, at 4:30 PM ET. During the call, Vanda’s management will discuss the second quarter 2020 financial results and other corporate activities. Investors can call 1-888-771-4371 (domestic) or 1-847-585-4405 (international) and use passcode 49854840.

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 Accepts and Grants Priority Review of Vanda's Applications for HETLIOZ® (tasimelteon) in the Treatment of Smith-Magenis Syndrome” issued on August 3, 2020. https://vandapharmaceuticalsinc.gcs-web.com/node/14226/pdf

[2] Carlin, J. L., Lieberman, V. R., Dahal, A., Keefe, M. S., Xiao, C., Birznieks, G., Abell, T. L., Lembo, A., Parkman, H., & Polymeropoulos, M. H. (2020). Efficacy and safety of tradipitant in patients with diabetic and idiopathic gastroparesis in a randomized, placebo-controlled trial. Gastroenterology. Advance online publication. https://doi.org/10.1053/j.gastro.2020.07.029

[3] Polymeropoulos, C. M., Mohrman, M. A., Keefe, M. S., Brzezynski, J. L., Wang, J., Prokosch, L. S., Polymeropoulos, V. M., Xiao, C., Birznieks, G., & Polymeropoulos, M. H. (2020). Efficacy of tasimelteon (Hetlioz®) in the treatment of jet lag disorder evaluated in an 8-h phase advance model; a multicenter, randomized, double-blind, placebo-controlled trial. Frontiers in Neurology, 11, 611. https://doi.org/10.3389/fneur.2020.00611

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 “2020 Financial Guidance” above and statements regarding Vanda’s ability to make HETLIOZ® available to patients with SMS, Vanda's marketing and sales strategies, the Individual Patient Expanded Access protocol for tradipitant, recruitment for the gastroparesis, motion sickness and ODYSSEY studies and clinical development and regulatory timelines for tradipitant and HETLIOZ® are “forward-looking statements” under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions 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 minimize the disruption caused by, and maintain business continuity during, the global COVID-19 pandemic and related market volatility; the duration and severity of the global COVID-19 pandemic, including prevailing economic conditions and general uncertainties relating thereto that may be unknown and unforeseeable; Vanda’s ability to enroll patients in and complete its gastroparesis, motion sickness and ODYSSEY studies; Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of gastroparesis, motion sickness, atopic dermatitis and COVID-19 ARDS; Vanda’s ability to successfully resume the clinical programs that are currently on hold and the FDA’s ability to complete its review of the HETLIOZ® applications for the treatment of SMS on time and make the determination that HETLIOZ® is safe and effective in the treatment of SMS in adults and children. There can be no assurance 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.

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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 2020	June 30 2019	June 30 2020	June 30 2019
Revenues:				
HETLIOZ® net product sales	$ 41,561	$ 37,835	$ 76,897	$ 66,792
Fanapt® net product sales	20,646	21,225	43,310	39,981
Total revenues	62,207	59,060	120,207	106,773
Operating expenses:				
Cost of goods sold excluding amortization	5,847	6,368	11,054	11,481
Research and development	12,903	10,950	28,430	24,228
Selling, general and administrative	33,917	31,468	70,938	62,497
Intangible asset amortization	369	379	739	759
Total operating expenses	53,036	49,165	111,161	98,965
Income from operations	9,171	9,895	9,046	7,808
Other income	1,918	1,649	3,284	3,134
Income before income taxes	11,089	11,544	12,330	10,942
Provision for income taxes	2,375	18	3,130	28
Net income	$ 8,714	$ 11,526	$ 9,200	$ 10,914
Net income per share, basic	$ 0.16	$ 0.22	$ 0.17	$ 0.21
Net income per share, diluted	$ 0.16	$ 0.21	$ 0.17	$ 0.20
Weighted average shares outstanding, basic	54,501,308	53,101,499	54,153,812	52,928,101
Weighted average shares outstanding, diluted	55,081,397	54,579,982	54,975,771	54,932,932

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

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,305	$ 45,072
Marketable securities	244,544	267,057
Accounts receivable, net	24,587	26,367
Inventory	1,384	1,140
Prepaid expenses and other current assets	15,041	14,500
Total current assets	380,861	354,136
Property and equipment, net	3,744	3,864
Operating lease right-of-use assets	10,601	11,180
Intangible assets, net	22,298	23,037
Deferred tax assets	85,558	87,680
Non-current inventory and other	3,569	3,851
Total assets	$ 506,631	$ 483,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 28,398	$ 27,590
Product revenue allowances	33,194	31,915
Total current liabilities	61,592	59,505
Operating lease non-current liabilities	11,720	12,455
Other non-current liabilities	1,735	843
Total liabilities	75,047	72,803
Stockholders' equity:		
Common stock	55	54
Additional paid-in capital	642,398	631,307
Accumulated other comprehensive income	596	249
Accumulated deficit	(211,465)	(220,665)
Total stockholders' equity	431,584	410,945
Total liabilities and stockholders' equity	$ 506,631	$ 483,748

Corporate Contact:

AJ Jones II
Chief Corporate Affairs and Communications Officer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Elizabeth Van Every
Head of Corporate Affairs
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

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