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): May 6, 2020

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

Delaware
(State or other jurisdiction of incorporation)

001-34186	**03-0491827**
(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 May 6, 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 March 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 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 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; the ability of Vanda and the University of Illinois at Chicago to identify small molecule inhibitors of cathepsin-L; Vanda's ability to enroll patients in and complete its ODYSSEY study; a failure of tradipitant to be demonstrably safe and effective in the treatment of COVID-19 Acute Respiratory Distress Syndrome ("ARDS"); Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of COVID-19 ARDS, atopic dermatitis, gastroparesis and motion sickness; Vanda's ability to successfully resume the clinical programs that are currently on hold; and other factors that are described in the "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, which is on file with the Securities and Exchange Commission ("SEC") and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Vanda's quarterly report on Form 10-Q for the quarter ended March 31, 2020, to be filed with the SEC in the second quarter of 2020. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. 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.

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.

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 May 6, 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: May 6, 2020

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Reports First Quarter 2020 Financial Results

- *Q1 2020 Total net product sales of $58.0 million, a 22% increase year over year*
- *Advancing the Commercial and Development Pipeline; Initiating Studies for COVID-19*

WASHINGTON – May 6, 2020 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2020.

“Our strong financial performance in the first quarter well positions Vanda to continue to innovate and serve our patients, even during this deadly pandemic,” said Mihael H. Polymeropoulos, M.D., Vanda’s President and CEO.

Key Financial and Corporate Highlights

- Total revenues from HETLIOZ® and Fanapt® were $58.0 million in the first quarter of 2020, a 22% increase compared to $47.7 million in the first quarter of 2019.
- HETLIOZ® net product sales were $35.3 million in the first quarter of 2020, a 22% increase compared to $29.0 million in the first quarter of 2019.
- Fanapt® net product sales were $22.7 million in the first quarter of 2020, a 21% increase compared to $18.8 million in the first quarter of 2019.
- Cash, cash equivalents and marketable securities (Cash) were $312.3 million as of March 31, 2020, representing an increase to Cash of $44.5 million compared to March 31, 2019.
- Net income was $0.5 million for the first quarter of 2020, compared to a net loss of $0.6 million for the first quarter of 2019.

Key Product and Pipeline Highlights

Vanda is working proactively across its business and research units to protect employees and customers, and to maintain business continuity as a result of the COVID-19 pandemic.

Products

Vanda is encouraged by the strong performance of its commercial products during the first quarter of 2020, driving 22% year-over-year growth. Vanda is implementing marketing and sales strategies aimed at overcoming the disruptions caused by the pandemic. Vanda remains committed to continue innovating and bringing value to patients and prescribers, while advancing and strengthening the awareness and use of its products.

Pipeline

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

Tradipitant

- The ongoing atopic dermatitis and gastroparesis studies have been adapted in accordance with U.S. Food and Drug Administration (FDA) guidance to protect the health and safety of currently enrolled patients and healthcare providers.
- The results of the recent atopic dermatitis (EPIONE), gastroparesis (VLY686-2301) and motion sickness (Motion Sifnos) studies have all been submitted to peer-review publications.
- See below for details on Vanda's clinical study, ODYSSEY VLY-686-3501, for the treatment of patients with COVID-19 Acute Respiratory Distress Syndrome (ARDS).

HETLIOZ® (tasimelteon)

- Discussions with the FDA are ongoing regarding the supplemental New Drug Applications for HETLIOZ® in the treatments of jet lag disorder and Smith-Magenis Syndrome.

COVID-19 Therapeutic Program

Vanda initiated the following activities aimed at combating COVID-19:

- Vanda announced the initiation of ODYSSEY VLY-686-3501, a Phase III double-blind placebo-controlled trial investigating the efficacy and safety of tradipitant for the treatment of patients with COVID-19 ARDS. Results of this study are expected in the third quarter of 2020.
- Vanda also announced the initiation of the CALYPSO genetics study to evaluate the role of human and viral genetic variations in COVID-19 infection and disease severity.
- Vanda and the University of Illinois at Chicago (UIC) announced a research partnership to identify small molecule inhibitors of cathepsin-L, a host enzyme required for viral processing.

GAAP Financial Results

Net income was $0.5 million for the first quarter of 2020, compared to a net loss of $0.6 million for the first quarter of 2019. Diluted net income per share was $0.01 in the first quarter of 2020, compared to a diluted net loss per share of $0.01 in the first quarter of 2019.

2020 Financial Guidance

Vanda will continue to assess the impact of the rapidly evolving COVID-19 pandemic on its business and operations and will provide future updates to its financial guidance as necessary. The financial guidance communicated by Vanda as of February 25, 2020 is shown below.

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 $320 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, May 6, 2020, at 4:30 PM ET. During the call, Vanda's management will discuss the first quarter 2020 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 2583625. A replay of the call will be available on Wednesday, May 6, 2020, beginning at 7:30 PM ET and will be accessible until Wednesday, May 13, 2020 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 2583625.

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.

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.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release, including, but not limited to, the guidance provided under "2020 Financial Guidance" above and statements regarding Vanda's ODYSSEY study, its collaboration with the UIC and its clinical development programs for tradipitant, HETLIOZ® and Fanapt®, 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 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; the ability of Vanda and the UIC to identify small molecule inhibitors of

cathepsin-L; Vanda's ability to enroll patients in and complete its ODYSSEY study; a failure of tradipitant to be demonstrably safe and effective in the treatment of COVID-19 ARDS; Vanda's ability to complete the clinical development and obtain regulatory approval for tradipitant in the treatment of COVID-19 ARDS, atopic dermatitis, gastroparesis and motion sickness; Vanda's ability to successfully resume the clinical programs that are currently on hold; and other factors that are described in the "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, which is on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Vanda's quarterly report on Form 10-Q for the quarter ended March 31, 2020, to be filed with the SEC in the second quarter of 2020. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. 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.

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 release is provided only as of the date of this 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.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended	
	March 31 2020	March 31 2019
Revenues:		
HETLIOZ® product sales, net	$ 35,336	$ 28,957
Fanapt® product sales, net	22,664	18,756
Total revenues	58,000	47,713
Operating expenses:		
Cost of goods sold excluding amortization	5,207	5,113
Research and development	15,527	13,278
Selling, general and administrative	37,021	31,029
Intangible asset amortization	370	380
Total operating expenses	58,125	49,800
Loss from operations	(125)	(2,087)
Other income	1,366	1,485
Income (loss) before income taxes	1,241	(602)
Provision for income taxes	755	10
Net income (loss)	$ 486	$ (612)
Net income (loss) per share, basic	$ 0.01	$ (0.01)
Net income (loss) per share, diluted	$ 0.01	$ (0.01)
Weighted average shares outstanding, basic	53,806,317	52,752,774
Weighted average shares outstanding, diluted	54,870,146	52,752,774

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

	March 31 2020	December 31 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,950	$ 45,072
Marketable securities	247,376	267,057
Accounts receivable, net	29,272	26,367
Inventory	1,320	1,140
Prepaid expenses and other current assets	17,828	14,500
Total current assets	360,746	354,136
Property and equipment, net	3,877	3,864
Operating lease right-of-use assets	10,875	11,180
Intangible assets, net	22,667	23,037
Deferred tax assets	86,641	87,680
Non-current inventory and other	3,719	3,851
Total assets	$ 488,525	$ 483,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 26,045	$ 27,590
Product revenue allowances	33,177	31,915
Total current liabilities	59,222	59,505
Operating lease non-current liabilities	12,139	12,455
Other non-current liabilities	778	843
Total liabilities	72,139	72,803
Stockholders' equity:		
Common stock	54	54
Additional paid-in capital	635,730	631,307
Accumulated other comprehensive income	781	249
Accumulated deficit	(220,179)	(220,665)
Total stockholders' equity	416,386	410,945
Total liabilities and stockholders' equity	$ 488,525	$ 483,748

Corporate Contact:

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