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 25, 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 February 25, 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 and full year ended December 31, 2019. 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 complete the clinical development and obtain regulatory approval for tradipitant in the treatment of motion sickness, gastroparesis and/or atopic dermatitis, Vanda's discussion and potential resolution of the deficiencies that the FDA believes are contained in the supplemental New Drug Application ("sNDA") for HETLIOZ® for the treatment of Jet Lag Disorder ("JLD") and Vanda's ability to obtain marketing approval for the use for HETLIOZ® in the treatment of JLD following any such resolution, Vanda's ability to complete the clinical development, submit an sNDA and obtain regulatory approval for tasimelteon in the treatment of sleep disorders in patients with Smith-Magenis Syndrome, Vanda's ability to complete the clinical development and obtain regulatory approval for Fanapt® in bi polar disorder and Fanapt® long acting injectible in schizophrenia 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, 2018 and quarterly report on Form 10-Q for the quarter ended September 30, 2019, which are 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 annual report on Form 10-K for the year ended December 31, 2019, to be filed with the SEC in the first 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 the Exhibit 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 25, 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: February 25, 2020

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results

- *Full year 2019 total revenues grew to $227.2 million, an 18% increase compared to 2018*
- *Full year 2020 total revenues expected to be between $240 million and $260 million*
- *Results from the EPIONE study of Tradipitant in the treatment of Pruritus in Atopic Dermatitis reported today*

WASHINGTON – February 25, 2020 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the fourth quarter and full year ended December 31, 2019.

"We had another year of outstanding commercial growth," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "I have never been more excited about the opportunities ahead with our relentless focus on developing innovative therapies for patients in need."

Key Financial Highlights

- Total revenues were $60.9 million in the fourth quarter of 2019, a 15% increase compared to $53.0 million in the fourth quarter of 2018. Total revenues were $227.2 million for the full year 2019, an 18% increase compared $193.1 million for the full year 2018.
- HETLIOZ® net product sales were $38.6 million in the fourth quarter of 2019, a 19% increase compared to $32.4 million in the fourth quarter of 2018. HETLIOZ® net product sales were $143.0 million for the full year 2019, a 23% increase compared to $115.8 million for the full year 2018.
- Fanapt® net product sales were $22.3 million in the fourth quarter of 2019, an 8% increase compared to $20.6 million in the fourth quarter of 2018. Fanapt® net product sales were $84.2 million for the full year 2019, a 9% increase compared to $77.3 million for the full year 2018.
- Cash, cash equivalents and marketable securities (Cash) were $312.1 million as of December 31, 2019, representing an increase to Cash of $54.8 million compared to December 31, 2018.

Key Product and Pipeline Highlights

Tradipitant

- Results from the EPIONE study of tradipitant in the treatment of pruritus in atopic dermatitis were reported today. Vanda will reassess EPIONE 2 and determine next steps.
- Enrollment in the Phase III study of tradipitant in gastroparesis (VP-VLY-686-3301) is ongoing.
- Vanda expects to complete the Phase III program of tradipitant in motion sickness and file a New Drug Application with the U.S. Food and Drug Administration (FDA) in 2020.
- Vanda continues to engage with the FDA over the requirement of a 9-month dog toxicity study.

HETLIOZ® (tasimelteon)

- Vanda submitted a supplemental New Drug Application (sNDA) for HETLIOZ® in Smith-Magenis Syndrome (SMS), including data for a liquid formulation, and expects regulatory action by the FDA in 2020.
- Vanda continues to pursue approval for HETLIOZ® in the treatment of jet lag disorder (JLD).
- A clinical program for HETLIOZ® in delayed sleep phase disorder (DSPD) is ongoing.

Fanapt® (iloperidone)

- A Phase III study of Fanapt® in bipolar disorder is ongoing.
- Development of the long acting injectable (LAI) formulation of Fanapt® is ongoing.

GAAP Financial Results

Net income was $4.2 million for the fourth quarter of 2019, compared to net income of $10.4 million for the fourth quarter of 2018. Diluted net income per share was $0.08 in the fourth quarter of 2019, compared to $0.19 in the fourth quarter of 2018.

Net income was $115.6 million for the full year 2019, compared to net income of $25.2 million, for the full year 2018. Diluted net income per share was $2.11 for the full year 2019, compared to $0.48 for the full year 2018. The income tax benefit of $86.5 million reflected in the financial results for the full year 2019 includes the favorable impact of the release of Vanda's deferred tax asset valuation allowance.

2020 Financial Guidance

Vanda expects to achieve the following financial objectives in 2020:

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, Tuesday, February 25, 2020, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 2019 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 2149683. A replay of the call will be available on Tuesday, February 25, 2020, beginning at 7:30 PM ET and will be accessible until Tuesday, March 3, 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 2149683.

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, 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 complete the clinical development and obtain regulatory approval for tradipitant in the treatment of motion sickness, gastroparesis and/or atopic dermatitis, Vanda's discussion and potential resolution of the deficiencies that the FDA believes are contained in the sNDA for HETLIOZ® for the treatment of JLD and Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of JLD following any such resolution, Vanda's ability to complete the clinical development, submit an sNDA and obtain regulatory approval for tasimelteon in the treatment of sleep disorders in patients with SMS, Vanda's ability to complete the clinical development and obtain regulatory approval for Fanapt® in bipolar disorder and Fanapt® LAI in schizophrenia, 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, 2018 and quarterly report on Form 10-Q for the quarter ended September 30, 2019, which are 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 annual report on Form 10-K for the year ended December 31, 2019, to be filed with the SEC in the first 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		Twelve Months Ended	
	December 31 2019	December 31 2018	December 31 2019	December 31 2018
Revenues:				
HETLIOZ® product sales, net	$ 38,599	$ 32,444	$ 142,980	$ 115,835
Fanapt® product sales, net	22,331	20,597	84,208	77,283
Total revenues	60,930	53,041	227,188	193,118
Operating expenses:				
Cost of goods sold excluding amortization	6,225	5,667	24,488	20,508
Research and development	13,074	12,922	48,649	43,594
Selling, general and administrative	37,018	24,922	129,736	105,751
Intangible asset amortization	370	380	1,505	1,527
Total operating expenses	56,687	43,891	204,378	171,380
Income from operations	4,243	9,150	22,810	21,738
Other income	1,567	1,168	6,218	3,608
Income before income taxes	5,810	10,318	29,028	25,346
Provision (benefit) for income taxes	1,594	(42)	(86,525)	138
Net income	$ 4,216	$ 10,360	$ 115,553	$ 25,208
Net income per share, basic	$ 0.08	$ 0.20	$ 2.17	$ 0.50
Net income per share, diluted	$ 0.08	$ 0.19	$ 2.11	$ 0.48
Weighted average shares outstanding, basic	53,389,950	52,457,275	53,137,562	50,859,947
Weighted average shares outstanding, diluted	54,973,952	55,216,507	54,847,060	53,045,257

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

	December 31 2019 (1)	December 31 2018 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,072	$ 61,005
Marketable securities	267,057	196,355
Accounts receivable, net	26,367	28,780
Inventory	1,140	994
Prepaid expenses and other current assets	14,500	11,998
Total current assets	354,136	299,132
Property and equipment, net	3,864	4,417
Operating lease right-of-use assets	11,180	—
Intangible assets, net	23,037	24,542
Deferred tax assets	87,680	—
Non-current inventory and other	3,851	4,039
Total assets	$ 483,748	$ 332,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 27,590	$ 21,584
Product revenue allowances	31,915	31,231
Milestone obligations under license agreements	—	200
Total current liabilities	59,505	53,015
Operating lease non-current liabilities	12,455	—
Other non-current liabilities	843	3,693
Total liabilities	72,803	56,708
Stockholders' equity:		
Common stock	54	52
Additional paid-in capital	631,307	611,587
Accumulated other comprehensive income	249	1
Accumulated deficit	(220,665)	(336,218)
Total stockholders' equity	410,945	275,422
Total liabilities and stockholders' equity	$ 483,748	$ 332,130

(1) With the adoption of Accounting Standards Codification Subtopic ASC 842, Leases, on January 1, 2019, Vanda recognized operating lease liabilities and right-of-use assets. Prior period financial statements were not recast for the new leasing standard. For more information, please refer to footnote 2 in the annual report on Form 10-K for the year ended December 31, 2019, to be filed in the first quarter of 2020.

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

SOURCE Vanda Pharmaceuticals Inc.