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 6, 2019

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 November 6, 2019, 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, 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 2019. 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 of tradipitant for the treatment of motion sickness, gastroparesis and/or chronic pruritus in atopic dermatitis; the outcome of the lawsuit initiated by Vanda against the FDA relating to tradipitant; 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 and Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of Jet Lag Disorder following any such resolution; Vanda's ability to complete the clinical development, submit an sNDA and obtain regulatory approval of tasimelteon for the treatment of sleep disorders in patients with Smith-Magenis Syndrome 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 June 30, 2019, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Vanda's quarterly report on Form 10-Q for the quarter ended September 30, 2019, to be filed with the SEC in the fourth quarter of 2019. In addition to the risks described above and in Vanda's annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, 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 November 6, 2019.
Exhibit 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 6, 2019

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Reports Third Quarter 2019 Financial Results

- *Q3 2019 Total net product sales of $59.5 million, a 21% increase year over year*
- *Vanda reiterates full year 2019 revenue guidance of $215 to $225 million and expects results in the upper half of the range*

WASHINGTON – November 6, 2019 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2019.

"These results affirm Vanda's corporate strategy, and continue to demonstrate our ability to grow our commercial assets and expand our pipeline of products," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "I am proud of the progress we have made in our research and development programs, with several new filings expected to be submitted within the next two years. Furthermore, Vanda has put in place a proactive regulatory strategy to better support our patients and products."

Key Financial Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were $59.5 million in the third quarter of 2019, a 21% increase compared to $49.1 million in the third quarter of 2018.
- HETLIOZ® net product sales were $37.6 million in the third quarter of 2019, a 26% increase compared to $29.9 million in the third quarter of 2018.
- Fanapt® net product sales were $21.9 million in the third quarter of 2019, a 14% increase compared to $19.2 million in the third quarter of 2018.
- Cash, cash equivalents and marketable securities (Cash) were $299.6 million as of September 30, 2019, representing an increase to Cash of $59.0 million compared to September 30, 2018.

Key Research and Development Highlights:

Tradipitant

- Enrollment in EPIONE, the Phase III clinical study of tradipitant in atopic dermatitis, is complete. Results from EPIONE are expected in the first quarter of 2020.
- In October 2019, EPIONE II, a second Phase III clinical study of tradipitant in atopic dermatitis, began enrolling patients.
- Enrollment in the Phase III study of tradipitant in gastroparesis is ongoing as Vanda continues to engage with the U.S. Food and Drug Administration (FDA) on tradipitant's regulatory path.
- Vanda plans to initiate the Phase III program of tradipitant in motion sickness in the fourth quarter of 2019. Vanda expects to file a New Drug Application with the FDA for tradipitant for the treatment of motion sickness in 2020.

HETLIOZ® (tasimelteon)

- Vanda received a complete response letter (CRL) on August 16, 2019 from the FDA related to the supplemental New Drug Application (sNDA) of HETLIOZ® for the treatment of Jet Lag Disorder (JLD). Vanda met with the FDA to discuss the CRL in a Post Action meeting and is determining its next steps.
- Vanda plans to meet with the FDA in the fourth quarter of 2019 to discuss the HETLIOZ® Smith-Magenis Syndrome clinical study results and expects to submit an sNDA by year-end 2019.
- An observational study of delayed sleep phase disorder (DSPD) is ongoing. Vanda plans to initiate a Phase III clinical study of HETLIOZ® in DSPD patients by year-end 2019.

Fanapt® (iloperidone)

- A pharmacokinetic study for the once-a-month long acting injectable (LAI) formulation of Fanapt® is ongoing.
- A study of Fanapt® in bipolar disorder is planned to begin by year-end 2019.

VTR-297 (histone deactetylase (HDAC) inhibitor)

- Enrollment in the Phase I clinical study (1101) of VTR-297 in hematologic malignancies is ongoing.

Corporate Highlights:

- Vanda announced the appointment of Anne Sempowski Ward to its Board of Directors, effective October 28, 2019, increasing the total number of members on the Board to six.
- Vanda announced the hiring of Scott L. Howell as its Chief People Officer, Aranthan “AJ” Jones II as its Chief Corporate Affairs and Communications Officer and Joakim “Kim” Wijkstrom as its Chief Marketing Officer, further bolstering the executive leadership team.

GAAP Financial Results

Net income was $100.4 million for the third quarter of 2019, or $1.88 per share, compared to net income of $7.2 million, or $0.14 per share, for the third quarter of 2018.

The income tax benefit of $88.1 million reflected in the financial results for the third quarter of 2019 includes the favorable impact of the release of Vanda’s deferred tax asset valuation allowance.

Income before income taxes was $12.3 million in the third quarter of 2019, a 69% increase compared to $7.3 million in the third quarter of 2018.

2019 Financial Guidance

Vanda reiterates its 2019 net product sales guidance and expects results in the upper half of the range. In addition, Vanda provides an update to Year-end 2019 Cash and expects to achieve the following financial objectives in 2019:

Full Year 2019 Financial Objectives	Full Year 2019 Guidance
Combined net product sales from both HETLIOZ® and Fanapt®	$215 to $225 million[1]
HETLIOZ® net product sales	$137 to $143 million[1]
Fanapt® net product sales	$78 to $82 million[1]
Year-end 2019 Cash	Greater than $295 million as compared to prior guidance of Greater than $275 million

1) Results expected in the upper half of the range

Conference Call

Vanda has scheduled a conference call for today, Wednesday, November 6, 2019, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 2019 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 5377942. A replay of the call will be available on Wednesday, November 6, 2019, beginning at 7:30 PM ET and will be accessible until Wednesday, November 13, 2019, 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 5377942.

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 "2019 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 of tradipitant for the treatment of motion sickness, gastroparesis and/or chronic pruritus in atopic dermatitis, the outcome of the lawsuit initiated by Vanda against the FDA relating to tradipitant, Vanda's discussion and potential resolution of the deficiencies that the FDA believes are contained in the sNDA for HETLIOZ® for the treatment of Jet Lag Disorder and Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of Jet Lag Disorder following any such resolution, Vanda's ability to complete the clinical development, submit an sNDA and obtain regulatory approval of tasimelteon for the treatment of sleep disorders in patients with Smith-Magenis Syndrome 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 June 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 quarterly report on Form 10-Q for the quarter ended September 30, 2019, to be filed with the SEC in the fourth quarter of 2019. 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.

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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		Nine Months Ended	
	September 30 2019	September 30 2018	September 30 2019	September 30 2018
Revenues:				
HETLIOZ® product sales, net	$ 37,589	$ 29,923	$ 104,381	$ 83,391
Fanapt® product sales, net	21,896	19,212	61,877	56,686
Total revenues	59,485	49,135	166,258	140,077
Operating expenses:				
Cost of goods sold excluding amortization	6,782	5,068	18,263	14,841
Research and development	11,347	11,390	35,575	30,672
Selling, general and administrative	30,221	26,047	92,718	80,829
Intangible asset amortization	376	397	1,135	1,147
Total operating expenses	48,726	42,902	147,691	127,489
Income from operations	10,759	6,233	18,567	12,588
Other income	1,517	1,030	4,651	2,440
Income before income taxes	12,276	7,263	23,218	15,028
Provision (benefit) for income taxes	(88,147)	92	(88,119)	180
Net income	$ 100,423	$ 7,171	$ 111,337	$ 14,848
Net income per share, basic	$ 1.88	$ 0.14	$ 2.10	$ 0.30
Net income per share, diluted	$ 1.84	$ 0.13	$ 2.03	$ 0.28
Weighted average shares outstanding, basic	53,297,298	52,389,012	53,052,521	50,321,640
Weighted average shares outstanding, diluted	54,541,625	54,709,749	54,803,851	52,315,642

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

	September 30 2019 (1)	December 31 2018 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,208	$ 61,005
Marketable securities	198,577	196,355
Accounts receivable, net	26,824	28,780
Inventory	1,019	994
Prepaid expenses and other current assets	14,382	11,998
Total current assets	280,010	299,132
Marketable securities, non-current	61,827	—
Property and equipment, net	4,156	4,417
Operating lease right-of-use assets	11,436	—
Intangible assets, net	23,407	24,542
Deferred tax assets	89,072	—
Non-current inventory and other	4,541	4,039
Total assets	$ 474,449	$ 332,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 26,992	$ 21,584
Product revenue allowances	33,004	31,231
Milestone obligations under license agreements	—	200
Total current liabilities	59,996	53,015
Operating lease non-current liabilities	12,793	—
Other non-current liabilities	753	3,693
Total liabilities	73,542	56,708
Stockholders' equity:		
Common stock	53	52
Additional paid-in capital	625,524	611,587
Accumulated other comprehensive income	211	1
Accumulated deficit	(224,881)	(336,218)
Total stockholders' equity	400,907	275,422
Total liabilities and stockholders' equity	$ 474,449	$ 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. Please refer to footnote 2 in the quarterly report on Form 10-Q for the quarter ended September 30, 2019, to be filed in the fourth quarter of 2019, for more information.

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