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 13, 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:

☐ 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))

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 13, 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 and year ended December 31, 2018. The full text of the press release which includes information regarding Vanda's use of Non-GAAP financial measures, 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 gastroparesis and/or the treatment of chronic pruritus in atopic dermatitis, the outcome of the lawsuit initiated by Vanda against the FDA relating to tradipitant, the ability of HETLIOZ® to provide significant benefit in the treatment of the symptoms of jet lag disorder, Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of jet lag disorder, Vanda's ability to complete the clinical development and obtain regulatory approval of tasimelteon for the treatment of sleep disorders in patients with SMS 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, 2017 and quarterly report on Form 10-Q for the quarter ended September 30, 2018, 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 annual report on Form 10-K for the year ended December 31, 2018, to be filed with the SEC in the first 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, 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. 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 13, 2019.

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 13, 2019

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Reports Fourth Quarter 2018 and Full Year 2018 Financial Results

- *Full year 2018 total revenues grew to $193.1 million, a 17% increase compared to 2017*
- *Full year 2019 total revenues expected to be between $215 million and $225 million*

WASHINGTON – February 13, 2019 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the fourth quarter and full year ended December 31, 2018.

"The combination of strong commercial performance and positive clinical results has set 2018 apart as a transformative year for Vanda," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "The tradipitant clinical programs in gastroparesis and atopic dermatitis have emerged as potentially significant drivers of future growth with the possibility of bringing new treatment options to millions of patients."

Key Financial Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were $53.0 million in the fourth quarter of 2018, an 8% increase compared to $49.1 million in the third quarter of 2018 and a 20% increase compared to $44.3 million in the fourth quarter of 2017.
- HETLIOZ® net product sales were $32.4 million in the fourth quarter of 2018, an 8% increase compared to $29.9 million in the third quarter of 2018 and a 30% increase compared to $25.0 million in the fourth quarter of 2017.
- Fanapt® net product sales were $20.6 million in the fourth quarter of 2018, a 7% increase compared to $19.2 million in the third quarter of 2018 and a 7% increase compared to $19.3 million in the fourth quarter of 2017.
- Cash, cash equivalents and marketable securities (Cash) were $257.4 million as of December 31, 2018, representing an increase to Cash of $113.9 million during 2018.

Research and Development Highlights:

Tradipitant – Clinical Development

- In December 2018, Vanda announced positive results from a Phase II clinical study (2301) of tradipitant in gastroparesis. Gastroparesis patients treated with tradipitant demonstrated significant improvement in nausea and most of the core gastroparesis symptoms.
- Vanda expects to meet with the U.S. Food and Drug Administration (the FDA) to further define and confirm the path towards approval of tradipitant in the treatment of patients with gastroparesis, including the planned initiation of a Phase III clinical study in the second quarter of 2019.
- Enrollment in the Phase III clinical study (EPIONE) of tradipitant in atopic dermatitis is ongoing. Results are expected in the first half of 2020. A second Phase III clinical study is expected to begin in the first quarter of 2020.
- In January 2019, Vanda initiated a Phase II clinical study of tradipitant in motion sickness. Study results are expected in the second quarter of 2019.

HETLIOZ® (tasimelteon)

- In December 2018, Vanda announced positive results from a clinical study of HETLIOZ® in Smith-Magenis Syndrome (SMS). SMS patients treated with HETLIOZ® demonstrated significant improvement in overall sleep quality and overall total nighttime sleep duration.
- Vanda expects to meet with the FDA in the second quarter of 2019 to confirm the regulatory path forward for HETLIOZ® in the treatment of patients with SMS and expects to file a supplemental New Drug Application (sNDA) in the third quarter of 2019.
- In December 2018, Vanda announced that the FDA had accepted the HETLIOZ® sNDA for the treatment of jet lag disorder with a Prescription Drug User Fee Act target action date of August 16, 2019.
- Vanda plans in the third quarter of 2019 to initiate a Phase II clinical study of HETLIOZ® in delayed sleep phase disorder (DSPD) in patients who have a mutation in the CRY1 gene which is believed to be causative in a subset of patients with the disorder.

Fanapt® (iloperidone)

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

VTR-297 (histone deactetylase (HDAC) inhibitor)

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

Tradipitant – Partial Clinical Hold and FDA Dispute

- In April 2018, Vanda submitted a protocol amendment to the FDA, proposing a 52-week open- label extension (OLE) period for patients who had completed the tradipitant Phase II clinical study (2301) in gastroparesis. In May 2018, based on feedback from the FDA, Vanda amended the protocol limiting the duration of treatment in the 2301 study to a total of three months, while continuing to seek further dialogue with the FDA on extending the study duration to 52-weeks. As a part of this negotiation process, in September 2018, Vanda submitted a new follow-on 52-week OLE protocol to the FDA (2302) for patients who had completed the 2301 study. While waiting for further feedback, no patients were ever enrolled in any study beyond 12 weeks.
- On December 19, 2018, the FDA imposed a partial clinical hold (PCH) on the two proposed studies, stating that Vanda is required first to conduct additional chronic toxicity studies in canines, monkeys or minipigs before allowing patients access in any clinical protocol beyond 12 weeks. The PCH was not based on any safety or efficacy data related to tradipitant. Rather, the FDA informed Vanda that these additional toxicity studies are required by a guidance document.
- On February 5, 2019, Vanda filed a lawsuit against the FDA in the United States District Court for the District of Columbia, challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside.
- Vanda does not expect the PCH to have any material impact on its ongoing clinical studies in atopic dermatitis and motion sickness or the planned Phase III study in gastroparesis. At present, the PCH has not had any impact on the potential timing of an NDA filing or approval for these indications. Vanda will continually reassess this situation as events unfold.

Non-GAAP Financial Results

Non-GAAP net income was $13.7 million for the fourth quarter of 2018, or $0.26 per share, compared to a Non-GAAP net income of $1.4 million, or $0.03 per share, for the fourth quarter of 2017. Vanda Non-GAAP net income was $38.4 million for the full year 2018, compared to a Non- GAAP net loss of $3.4 million for the full year 2017.

Vanda provides Non-GAAP financial information, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP figures. Refer to the sections of this press release entitled “Non-GAAP Financial Information” and “Reconciliation of GAAP to Non-GAAP Financial Information” for more detailed information regarding Non-GAAP financial information.

2019 Financial Guidance

Vanda 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
HETLIOZ® net product sales	$137 to $143 million
Fanapt® net product sales	$78 to $82 million
Year-end 2019 Cash	Greater than $260 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, February 13, 2019, at 4:30 PM ET. During the call, Vanda’s management will discuss the fourth quarter and full year 2018 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 1579398. A replay of the call will be available on Wednesday, February 13, 2019, beginning at 7:30 PM ET and will be accessible until Wednesday, February 20, 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 1579398.

The conference call will be broadcast simultaneously on Vanda’s website, www.vandapharma.com. Investors should click on the Investor Relations 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.

Non-GAAP Financial Information

Vanda believes that the Non-GAAP financial information provided in this press release can assist investors in understanding and assessing the ongoing economics of Vanda’s business and reflect how it manages the business internally and sets operational goals. Vanda’s “Non-GAAP Selling, general and administrative expenses” and “Non-GAAP Research and development expenses” exclude stock-based compensation. Vanda’s “Non-GAAP Net income (loss),” “Non-GAAP Net income (loss) per share” and “Non-GAAP Operating expenses excluding Cost of goods sold” exclude stock-based compensation and intangible asset amortization.

Vanda believes that excluding the impact of these items better reflects the recurring economic characteristics of its business, as well as Vanda’s use of financial resources and its long-term performance.

These Non-GAAP financial measures, as presented, may not be comparable to similarly titled measures reported by other companies since not all companies may calculate these measures in an identical manner and, therefore, they are not necessarily an accurate measure of comparison between companies.

The presentation of these Non-GAAP financial measures is not intended to be considered in isolation or as a substitute for guidance prepared in accordance with GAAP. The principal limitation of these Non-GAAP financial measures is that they exclude significant elements that are required by GAAP to be recorded in Vanda's financial statements. In addition, they are subject to inherent limitations as they reflect the exercise of judgments by management in determining these Non-GAAP financial measures. In order to compensate for these limitations, Vanda presents its Non-GAAP financial guidance in connection with its GAAP guidance. Investors are encouraged to review the reconciliation of our Non-GAAP financial measures to their most directly comparable GAAP financial measure.

About Vanda Pharmaceuticals Inc.

Vanda is a 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 gastroparesis and/or the treatment of chronic pruritus in atopic dermatitis, the outcome of the lawsuit initiated by Vanda against the FDA relating to tradipitant, the ability of HETLIOZ® to provide significant benefit in the treatment of the symptoms of jet lag disorder, Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of jet lag disorder, Vanda's ability to complete the clinical development and obtain regulatory approval of tasimelteon for the treatment of sleep disorders in patients with SMS 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, 2017 and quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2018, 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 fiscal year ended December 31, 2018, to be filed with the SEC in the first 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.

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 2018	December 31 2017	December 31 2018	December 31 2017
Revenues:				
HETLIOZ® product sales, net	$ 32,444	$ 25,010	$ 115,835	$ 89,978
Fanapt® product sales, net	20,597	19,266	77,283	75,105
Total revenues	53,041	44,276	193,118	165,083
Operating expenses:				
Cost of goods sold excluding amortization	5,667	4,791	20,508	17,848
Research and development	12,922	10,154	43,594	38,547
Selling, general and administrative	24,922	31,049	105,751	123,841
Intangible asset amortization	380	432	1,527	1,750
Total operating expenses	43,891	46,426	171,380	181,986
Income (loss) from operations	9,150	(2,150)	21,738	(16,903)
Other income	1,168	399	3,608	1,472
Income (loss) before income taxes	10,318	(1,751)	25,346	(15,431)
Provision (benefit) for income taxes	(42)	87	138	136
Net income (loss)	$ 10,360	$ (1,838)	$ 25,208	$ (15,567)
Net income (loss) per share, basic	$ 0.20	$ (0.04)	$ 0.50	$ (0.35)
Net income (loss) per share, diluted	$ 0.19	$ (0.04)	$ 0.48	$ (0.35)
Weighted average shares outstanding, basic	52,457,275	44,930,832	50,859,947	44,735,146
Weighted average shares outstanding, diluted	55,216,507	44,930,832	53,045,257	44,735,146

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

	December 31 2018 (1)	December 31 2017 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,005	$ 33,627
Marketable securities	196,355	109,786
Accounts receivable, net	28,780	17,601
Inventory	994	840
Prepaid expenses and other current assets	11,998	8,003
Total current assets	299,132	169,857
Property and equipment, net	4,417	5,306
Intangible assets, net	24,542	26,069
Non-current inventory and other	4,039	4,193
Total assets	$ 332,130	$ 205,425
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 21,584	$ 20,335
Product revenue allowances	31,231	23,028
Milestone obligations under license agreements	200	27,000
Total current liabilities	53,015	70,363
Other non-current liabilities	3,693	3,675
Total liabilities	56,708	74,038
Stockholders' equity:		
Common stock	52	45
Additional paid-in capital	611,587	492,802
Accumulated other comprehensive income (loss)	1	(34)
Accumulated deficit	(336,218)	(361,426)
Total stockholders' equity	275,422	131,387
Total liabilities and stockholders' equity	$ 332,130	$ 205,425

(1) With the adoption of Accounting Standards Codification Subtopic 606, *Revenue from Contracts with Customers*, on January 1, 2018, provision for product returns is included in product revenue allowances and other non-current liabilities in the current year. Provision for product returns is included in accounts receivable, net in the prior year. Please refer to footnote 2 in the annual report on Form 10-K for the year ended December 31, 2018, to be filed in the first quarter of 2019, for more information.

VANDA PHARMACEUTICALS INC.
Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31 2018	December 31 2017	December 31 2018	December 31 2017
Net income (loss)	$ 10,360	$ (1,838)	$ 25,208	$ (15,567)
Adjustments:				
Stock-based compensation	2,922	2,782	11,666	10,465
Intangible asset amortization	380	432	1,527	1,750
Non-GAAP Net income (loss)	$ 13,662	$ 1,376	$ 38,401	$ (3,352)
Non-GAAP Net income (loss) per share, basic	$ 0.26	$ 0.03	$ 0.76	$ (0.07)
Weighted average shares outstanding, basic	52,457,275	44,930,832	50,859,947	44,735,146
Operating expenses	$ 43,891	$ 46,426	$ 171,380	$ 181,986
Adjustments:				
Cost of goods sold excluding amortization	(5,667)	(4,791)	(20,508)	(17,848)
Stock-based compensation	(2,922)	(2,782)	(11,666)	(10,465)
Intangible asset amortization	(380)	(432)	(1,527)	(1,750)
Non-GAAP Operating expenses excluding Cost of goods sold	$ 34,922	$ 38,421	$ 137,679	$ 151,923
Research and development	$ 12,922	$ 10,154	$ 43,594	$ 38,547
Adjustment:				
Stock-based compensation	(327)	(194)	(1,290)	(1,152)
Non-GAAP Research and development	$ 12,595	$ 9,960	$ 42,304	$ 37,395
Selling, general and administrative	$ 24,922	$ 31,049	$ 105,751	$ 123,841
Adjustment:				
Stock-based compensation	(2,595)	(2,588)	(10,376)	(9,313)
Non-GAAP Selling, general and administrative	$ 22,327	$ 28,461	$ 95,375	$ 114,528

COMPANY CONTACT:
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SOURCE Vanda Pharmaceuticals Inc.