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 1, 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.001	**VNDA**	**The Nasdaq Stock Market LLC (Nasdaq Global Market)**

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 May 1, 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 March 31, 2019. 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, submit an supplemental new drug application 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, which is 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-K for the quarter ended March 31, 2019, to be filed with the SEC in the second 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 May 1, 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: May 1, 2019

VANDA PHARMACEUTICALS INC.

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

Vanda Pharmaceuticals Reports First Quarter 2019 Financial Results

- *Total net product sales of $47.7 million in the first quarter of 2019, a 9% increase year over year*
- *Vanda reiterates 2019 net product sales guidance of $215 million to $225 million*

WASHINGTON – May 1, 2019 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2019.

"During the first quarter, Vanda made significant advances towards its commercial and research goals. Patients on treatment with Hetlioz continue to increase steadily, driven by broader awareness and recognition of Non-24. We are preparing for a possible launch later this year in jet lag disorder, an indication that has the potential to drive significant growth for our Hetlioz franchise. Tradipitant clinical development is advancing for three indications, atopic dermatitis, gastroparesis and motion sickness," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "We believe that Vanda is well positioned for significant growth in the coming quarters and years given its strong commercial and clinical development pipeline and its exceptional people."

Key Financial Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were $47.7 million in the first quarter of 2019, a 10% decrease compared to $53.0 million in the fourth quarter of 2018 and a 9% increase compared to $43.6 million in the first quarter of 2018.
- HETLIOZ® net product sales were $29.0 million in the first quarter of 2019, an 11% decrease compared to $32.4 million in the fourth quarter of 2018 and a 14% increase compared to $25.4 million in the first quarter of 2018. In the first quarter of 2019, HETLIOZ® units sold to patients declined by 2% compared to the fourth quarter of 2018.
- Fanapt® net product sales were $18.8 million in the first quarter of 2019, a 9% decrease compared to $20.6 million in the fourth quarter of 2018 and a 3% increase compared to $18.2 million in the first quarter of 2018. In the first quarter of 2019, Fanapt® prescriptions, as reported by IQVIA, declined by 5% compared to the fourth quarter of 2018.
- Cash, cash equivalents and marketable securities (Cash) were $267.8 million as of March 31, 2019, representing an increase to Cash of $10.5 million and $19.0 million as compared to December 31, 2018 and March 31, 2018, respectively.

Key Research and Development Highlights:

Tradipitant – Clinical Development

- Vanda plans to meet with the U.S. Food and Drug Administration (the FDA) in the second quarter of 2019 to further define and confirm the path towards approval of tradipitant in the treatment of patients with gastroparesis.
- Vanda plans to initiate a Phase III clinical study of tradipitant in gastroparesis 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 third quarter of 2019.

HETLIOZ® (tasimelteon)

- The HETLIOZ® supplemental New Drug Application (sNDA) for the treatment of jet lag disorder is under review by the FDA with a Prescription Drug User Fee Act target action date of August 16, 2019.
- Vanda expects to meet with the FDA in the third quarter of 2019 to confirm the regulatory path forward for HETLIOZ® in the treatment of patients with SMS and expects to file an sNDA in the third quarter of 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 DSPD.

Fanapt® (iloperidone)

- Enrollment is ongoing in a pharmacokinetic study for the once-a-month long acting injectable (LAI) formulation of Fanapt®.
- 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. In December 2018, the FDA imposed a partial clinical hold (PCH) on two of Vanda's proposed clinical studies of tradipitant, 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 original 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.

In February 2019, Vanda filed a lawsuit against the FDA in the United States District Court for the District of Columbia (DC District Court), challenging the FDA's legal authority to issue the PCH, and seeking an order to set it aside. On February 14, 2019, the FDA filed a Motion for Voluntary Remand to the Agency and for a Stay of the Case. On March 14, 2019, the DC District Court granted the FDA's request for voluntary remand and returned the matter to the FDA for further consideration. On April 26, 2019, the FDA provided its remand response, in which it indicated that, after re-evaluation, it believes a partial clinical hold continues to be appropriate. After reviewing the FDA's remand response, Vanda continues to believe that additional chronic toxicity studies are unjustified, and that Vanda has provided the FDA with sufficient information regarding the safety of tradipitant to justify the continued study of tradipitant in patients beyond 12 weeks, in accordance with applicable law and FDA regulations. On April 29, 2019, Vanda and the FDA filed a Joint Motion for Extension of Time to Propose a Scheduling Order for this matter. On April 30, 2019, the DC District Court granted the motion, thereby extending the deadline until May 3, 2019 for the FDA and Vanda to file proposals regarding a scheduling order. Vanda intends to continue vigorously pursuing its interests in the matter.

Vanda does not expect the PCH to have any impact on its ongoing clinical studies in atopic dermatitis and motion sickness, each of which is under 12 weeks in duration, or its planned 12-week Phase III study in gastroparesis, none of which are subject to the PCH. Nor does Vanda expect the PCH to impact the potential timing of a New Drug Application (NDA) filing. If the matter has not been fully resolved prior to the date on which Vanda is ready to file the first NDA for tradipitant, then Vanda may choose to file with the safety data it has available at that time. Vanda may pursue additional studies of durations in excess of 12 weeks in countries where the conduct of such studies may be permitted (or it may choose to file for approval of a limited indication). If the FDA determines that Vanda's NDA does not contain safety data sufficient for approval, it may not accept the NDA for filing. Vanda will continue to reassess the situation as events unfold.

Non-GAAP Financial Results

Non-GAAP net income was $3.0 million for the first quarter of 2019, or $0.06 per share, compared to a Non-GAAP net income of $6.6 million, or $0.14 per share, for the first quarter of 2018.

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 reiterates its prior 2019 financial guidance 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
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, May 1, 2019, at 4:30 PM ET. During the call, Vanda's management will discuss the first 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 6195579. A replay of the call will be available on Wednesday, May 1, 2019, beginning at 7:00 PM ET and will be accessible until Wednesday, May 8, 2019, at 11:59 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 6195579.

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, submit an sNDA 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, 2018, 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, 2019, to be filed with the SEC in the second 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	
	March 31 2019	**March 31 2018**
Revenues:		
HETLIOZ® product sales, net	$ 28,957	$ 25,423
Fanapt® product sales, net	18,756	18,169
Total revenues	47,713	43,592
Operating expenses:		
Cost of goods sold excluding amortization	5,113	4,560
Research and development	13,278	9,416
Selling, general and administrative	31,029	26,822
Intangible asset amortization	380	352
Total operating expenses	49,800	41,150
Income (loss) from operations	(2,087)	2,442
Other income	1,485	622
Income (loss) before income taxes	(602)	3,064
Provision (benefit) for income taxes	10	(2)
Net income (loss)	$ (612)	$ 3,066
Net income (loss) per share, basic	$ (0.01)	$ 0.07
Net income (loss) per share, diluted	$ (0.01)	$ 0.06
Weighted average shares outstanding, basic	52,752,774	46,336,430
Weighted average shares outstanding, diluted	52,752,774	48,225,041

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

	March 31 2019 (1)	December 31 2018 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,379	$ 61,005
Marketable securities	233,457	196,355
Accounts receivable, net	26,346	28,780
Inventory	1,112	994
Prepaid expenses and other current assets	11,204	11,998
Total current assets	306,498	299,132
Property and equipment, net	4,294	4,417
Operating lease right-of-use assets	11,994	—
Intangible assets, net	24,162	24,542
Non-current inventory and other	4,218	4,039
Total assets	$ 351,166	$ 332,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 27,423	$ 21,584
Product revenue allowances	31,852	31,231
Milestone obligations under license agreements	—	200
Total current liabilities	59,275	53,015
Operating lease non-current liabilities	13,324	—
Other non-current liabilities	162	3,693
Total liabilities	72,761	56,708
Stockholders' equity:		
Common stock	53	52
Additional paid-in capital	615,047	611,587
Accumulated other comprehensive income	135	1
Accumulated deficit	(336,830)	(336,218)
Total stockholders' equity	278,405	275,422
Total liabilities and stockholders' equity	$ 351,166	$ 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 March 31, 2019, to be filed in the second 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	
	March 31 2019	March 31 2018
Net income (loss)	$ (612)	$ 3,066
Adjustments:		
Stock-based compensation	3,282	3,151
Intangible asset amortization	380	352
Non-GAAP Net income	$ 3,050	$ 6,569
Non-GAAP Net income per share, basic	$ 0.06	$ 0.14
Weighted average shares outstanding, basic	52,752,774	46,336,430
Operating expenses	$ 49,800	$ 41,150
Adjustments:		
Cost of goods sold excluding amortization	(5,113)	(4,560)
Stock-based compensation	(3,282)	(3,151)
Intangible asset amortization	(380)	(352)
Non-GAAP Operating expenses excluding Cost of goods sold	$ 41,025	$ 33,087
Research and development	$ 13,278	$ 9,416
Adjustment:		
Stock-based compensation	(728)	(321)
Non-GAAP Research and development	$ 12,550	$ 9,095
Selling, general and administrative	$ 31,029	$ 26,822
Adjustment:		
Stock-based compensation	(2,554)	(2,830)
Non-GAAP Selling, general and administrative	$ 28,475	$ 23,992

COMPANY CONTACT:

Jim Kelly
Executive Vice President & Chief Financial Officer
Vanda Pharmaceuticals Inc.
(202) 734-3428
jim.kelly@vandapharma.com

SOURCE Vanda Pharmaceuticals Inc.