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 5, 2022

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

Delaware	**001-34186**	**03-0491827**
(State or other jurisdiction of incorporation)	**(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 5, 2022, 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, 2022. 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 2022, and statements regarding Vanda's commercial products, plans and opportunities, as well as statements about Vanda's products in development and the related clinical development and regulatory timelines and commercial potential for such products. 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 and assumptions that involve risks, changes in circumstances 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 the strength of its business in the U.S. and Vanda's ability to complete the clinical development of, and obtain regulatory approval for, tradipitant in the treatment of gastroparesis. Therefore, no assurance can be given 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. Forward-looking statements made during the call should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "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, 2021, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

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, except as required by law.

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 5, 2022.
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 5, 2022

VANDA PHARMACEUTICALS INC.

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

Exhibit 99.1

Vanda Pharmaceuticals Reports First Quarter 2022 Financial Results

WASHINGTON – May 5, 2022 /PRNewswire/ – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2022.

"We are excited with our progress in improving patient access for HETLIOZ®, especially for Medicaid beneficiaries with Non-24 and SMS diagnoses," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "Further, we now anticipate completing enrollment of the Fanapt® bipolar disorder study by the end of this year and look forward to expanding our psychiatry franchise. Today we are sharing details of our advanced analysis of data from the tradipitant clinical program in gastroparesis, which support the efficacy of tradipitant, and we look forward to discussing our planned New Drug Application with the FDA."

Financial Highlights

- Total net product sales from HETLIOZ® and Fanapt® were $60.2 million in the first quarter of 2022, a 4% decrease compared to $62.7 million in the first quarter of 2021.
- HETLIOZ® net product sales were $37.0 million in the first quarter of 2022, a 6% decrease compared to $39.3 million in the first quarter of 2021, due in part to the continued reimbursement challenges for prescriptions for patients with Non-24.
- Fanapt® net product sales were $23.2 million in the first quarter of 2022, a 1% decrease compared to $23.3 million in the first quarter of 2021.
- Net loss was $6.4 million in the first quarter of 2022 compared to net income of $8.7 million in the first quarter of 2021.
- Cash, cash equivalents and marketable securities (Cash) was $435.2 million as of March 31, 2022, representing an increase to Cash of $57.0 million compared to March 31, 2021 and an increase to Cash of $2.4 million compared to December 31, 2021.

Key Operational Highlights

HETLIOZ® (tasimelteon)

- Clinical trials for HETLIOZ® in delayed sleep phase disorder (DSPD) and symptoms of autism spectrum disorder (ASD) are currently enrolling patients.
- Since November 2021, more than 15 states have revised or agreed to revise their Medicaid prior authorization criteria to broaden access to HETLIOZ® for patients with Non-24 and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).
- In January 2022, Vanda settled its HETLIOZ® patent litigation against one of the defendants. The trial for the consolidated lawsuit against the remaining defendants was held in March 2022. A decision is expected from the court in the second half of 2022.

Tradipitant

Tradipitant is a neurokinin-1 (NK-1) receptor antagonist in development for the treatment of idiopathic and diabetic gastroparesis. Earlier in the year, Vanda reported results of a clinical study and initial exploratory analysis. Vanda has now completed a pooled analysis of two clinical studies of tradipitant in gastroparesis consisting of 342 patients with relevant clinical endpoints. We believe these studies are adequate and well controlled and support substantial evidence of efficacy of tradipitant. Figure 1 and Table 1 show the results of such pooled analysis of all patients randomized in the two studies (intent to

treat population, ITT) and Figure 2 and Table 2 show the results for the same parameters in the population of patients who were judged as compliant to treatment based on analysis of drug exposure (treatment compliant population).

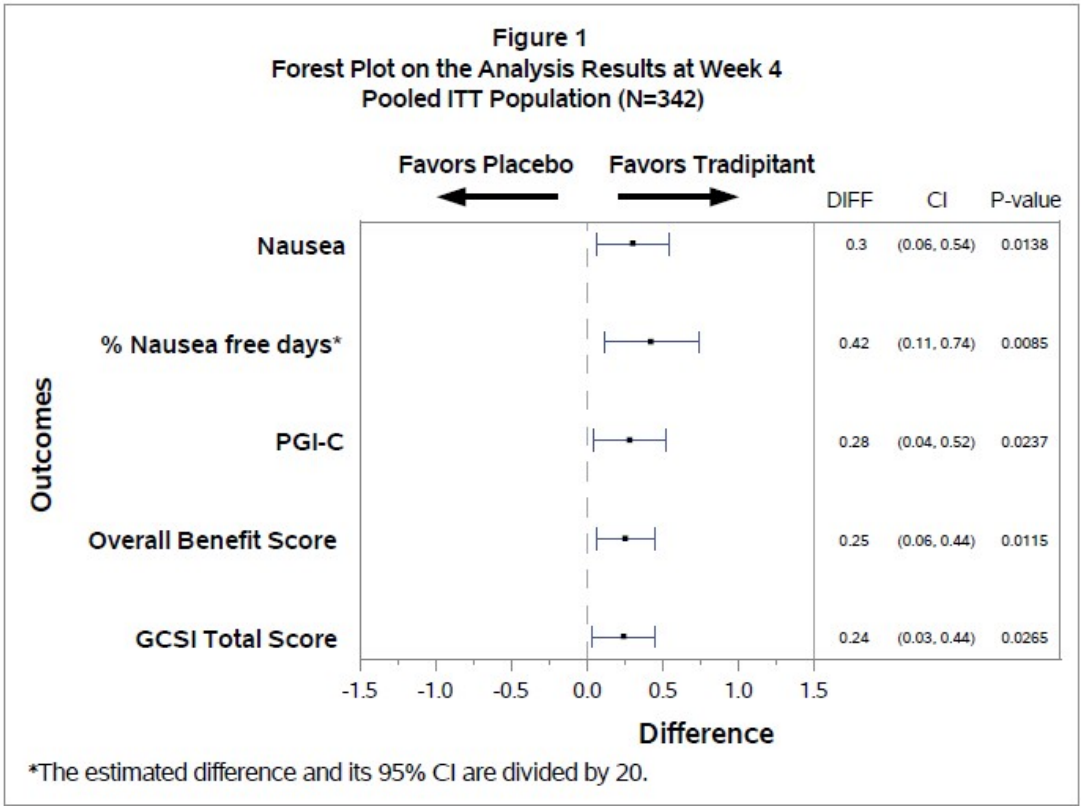

Table 1: Week 4 Pooled Analysis: ITT Population for Study 1 and Study 2

	Tradipitant n=175	Placebo n=167	P-value
DD-Nausea	-1.15	-0.85	0.0138
% Nausea Free Days	20.96	12.52	0.0085
PGI-C	2.72	3.00	0.0237
Overall Benefit Score	1.13	0.88	0.0115
GCSI	-0.99	-0.76	0.0265

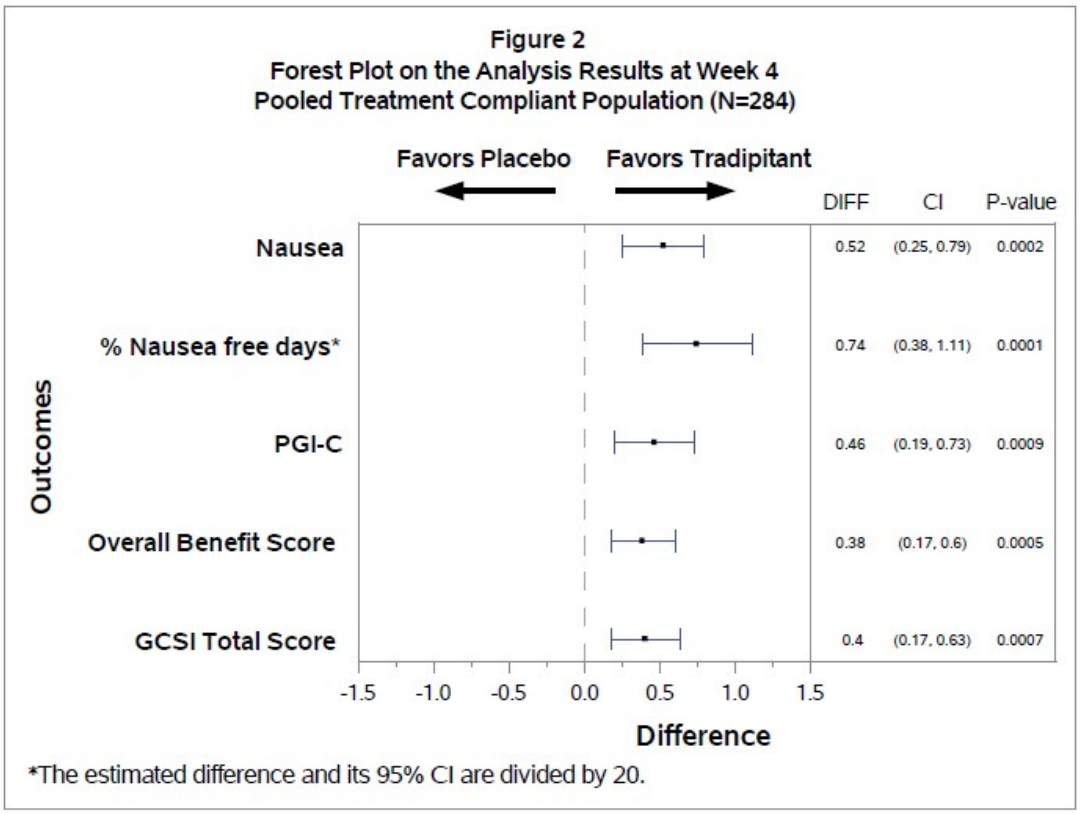

Table 2: Week 4 Pooled Analysis: Treatment Compliant Population for Study 1 and Study 2

	Tradipitant n=117	Placebo n=167	P-value
DD-Nausea	-1.37	-0.85	0.0002
% Nausea Free Days	27.44	12.58	0.0001
PGI-C	2.53	2.99	0.0009
Overall Benefit Score	1.27	0.88	0.0005
GCSI	-1.15	-0.75	0.0007

Consistently, both pooled analyses show tradipitant to be superior to placebo in key clinical parameters including improvement in DD-Nausea (primary endpoint parameter), percent Nausea Free Days, Patient Global Impression scale change (PGI-C), Overall Benefit Score and Gastroparesis Cardinal Symptom Index (GCSI) score.

- Vanda is continuing to conduct an open-label study of safety for tradipitant in gastroparesis and continues to receive requests from patients reaching out to gain access to tradipitant through the Expanded Access program which has multiple patients continuing to take tradipitant for more than a year.
- Vanda has scheduled a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) to discuss the planned New Drug Application submission for tradipitant in the short-term treatment of nausea in gastroparesis.
- The Phase III study of tradipitant in the treatment of motion sickness has restarted enrollment and is already over 15% enrolled. A prior Phase II study of tradipitant in the treatment of motion sickness observed a significantly lower incidence of vomiting in tradipitant-treated patients as compared to placebo-treated patients.

Fanapt® (iloperidone)

- A Phase III study of Fanapt® in acute manic episodes in patients with bipolar disorder is over 75% enrolled and expected to complete enrollment by the end of 2022.

GAAP Financial Results

Net loss was $6.4 million in the first quarter of 2022 compared to net income of $8.7 million in the first quarter of 2021. Diluted net loss per share was $0.11 in the first quarter of 2022 compared to diluted net income per share of $0.15 in the first quarter of 2021.

2022 Financial Guidance

Vanda expects to achieve the following financial objectives in 2022**:**

Full Year 2022 Financial Objectives	Full Year 2022 Guidance
Total revenues	$240 to $280 million
HETLIOZ® net product sales	$150 to $180 million
Fanapt® net product sales	$90 to $100 million
Year-end 2022 Cash	Greater than $440 million

Conference Call

Vanda has scheduled a conference call for today, Thursday, May 5, 2022, at 4:30 PM ET. During the call, Vanda's management will discuss the first quarter 2022 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode number 1355275. A replay of the call will be available on Thursday, May 5, 2022, beginning at 7:30 PM ET and will be accessible until Thursday, May 12, 2022 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 1355275.

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 and follow us on Twitter @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, the guidance provided under "2022 Financial Guidance" above and statements regarding Vanda's plans for continued pursuit of regulatory approval of tradipitant for the treatment of gastroparesis, the timing of the court's decision with respect to the Company's HETLIOZ® patent litigation and the clinical development timelines for Fanapt® are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances 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 the strength of its business in the U.S., the FDA's willingness to meet with Vanda to discuss the planned NDA submission for tradipitant and Vanda's ability to complete enrollment of the Phase III clinical study of Fanapt® in bipolar disorder. Therefore, no assurance can be given that the 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. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "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, 2021, as updated by Vanda's

subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

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 press release is provided only as of the date of this press 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, except as required by law.

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

	Three Months Ended	
	March 31 2022	**March 31 2021**
Revenues:		
HETLIOZ® net product sales	$ 37,031	$ 39,343
Fanapt® net product sales	23,161	23,326
Total revenues	60,192	62,669
Operating expenses:		
Cost of goods sold excluding amortization	5,665	6,030
Research and development	20,969	16,131
Selling, general and administrative	40,848	29,797
Intangible asset amortization	379	370
Total operating expenses	67,861	52,328
Income (loss) from operations	(7,669)	10,341
Other income	105	87
Income (loss) before income taxes	(7,564)	10,428
Provision (benefit) for income taxes	(1,134)	1,778
Net income (loss)	$ (6,430)	$ 8,650
Net income (loss) per share, basic	$ (0.11)	$ 0.16
Net income (loss) per share, diluted	$ (0.11)	$ 0.15
Weighted average shares outstanding, basic	56,105,239	55,145,789
Weighted average shares outstanding, diluted	56,105,239	56,505,087

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

	March 31 2022	December 31 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,927	$ 52,071
Marketable securities	368,249	380,742
Accounts receivable, net	30,497	32,467
Inventory	1,290	1,025
Prepaid expenses and other current assets	25,305	11,996
Total current assets	492,268	478,301
Property and equipment, net	2,917	3,113
Operating lease right-of-use assets	8,945	9,272
Intangible assets, net	19,702	20,081
Deferred tax assets	70,798	74,878
Non-current inventory and other	8,928	8,147
Total assets	$ 603,558	$ 593,792
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 51,394	$ 34,438
Product revenue allowances	39,348	39,981
Total current liabilities	90,742	74,419
Operating lease non-current liabilities	9,660	10,055
Other non-current liabilities	1,033	4,390
Total liabilities	101,435	88,864
Stockholders' equity:		
Common stock	56	56
Additional paid-in capital	674,001	669,223
Accumulated other comprehensive loss	(1,328)	(175)
Accumulated deficit	(170,606)	(164,176)
Total stockholders' equity	502,123	504,928
Total liabilities and stockholders' equity	$ 603,558	$ 593,792

Corporate Contact:

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