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 8, 2024

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(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**VNDA**	**The Nasdaq Global Market**
Series A Junior Participating Preferred Stock Purchase Right, par value $0.001 per share	**-**	**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 8, 2024, 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, 2024 (the "Earnings Call"). 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 Earnings Call are "forward-looking statements" under the securities laws, including, but not limited to, 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. 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. and Vanda's ability to complete the clinical development of, and obtain regulatory approval for, the products in its pipeline. 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 Earnings 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 most recent Annual Report on Form 10-K, 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 Earnings Call will be provided only as of the date thereof, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the Earnings 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 8, 2024.
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 8, 2024

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 2024 Financial Results

- *Revenues for Q1 2024 were $47.5 million, an increase of 5% compared to Q4 2023*
- *Cash increase of $5.9 million in Q1 2024 to $394.1 million*
- *Fanapt® approved for the acute treatment of bipolar I disorder; commercial launch expected in Q3 2024*
- *Milsaperidone NDA for schizophrenia and bipolar disorder expected to be submitted in early-2025*
- *PONVORY® commercial launch expected in Q3 2024*
- *Tradipitant NDA review for gastroparesis ongoing, PDUFA date of September 18, 2024*
- *Tradipitant second Phase III motion sickness study results expected in Q2 2024; NDA expected to be submitted in Q4 2024*

WASHINGTON – May 8, 2024 – Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2024.

"We are very proud of our accomplishments in the first quarter of 2024, which were achieved with a small but efficient organization that is enthusiastic to continue developing and commercializing treatments for people who need them," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "We expect several significant milestones in the coming months, including the launch of Fanapt in acute bipolar I disorder, the launch of Ponvory in multiple sclerosis, the potential approval of tradipitant in gastroparesis, the phase III results of tradipitant in motion sickness, the upcoming NDA filings of milsaperidone in psychiatric disorders and of tradipitant in motion sickness and the initiation of clinical programs in depression, psoriasis, ulcerative colitis and pediatric insomnia. We are confident that our robust revenue, strong cash position and efficient operations position us well for significant growth and value creation in the years to come."

Financial Highlights

- Total net product sales from Fanapt®, HETLIOZ® and PONVORY® were $47.5 million in the first quarter of 2024, a 24% decrease compared to $62.5 million in the first quarter of 2023, and a 5% increase compared to $45.3 million in the fourth quarter of 2023.
- Fanapt® net product sales were $20.6 million in the first quarter of 2024, a 10% decrease compared to $22.9 million in the first quarter of 2023, and a 9% decrease compared to $22.6 million in the fourth quarter of 2023.
- HETLIOZ® net product sales were $20.1 million in the first quarter of 2024, a 49% decrease compared to $39.6 million in the first quarter of 2023, and a 5% decrease compared to $21.1 million in the fourth quarter of 2023. The decrease relative to the first quarter of 2023 was the result of continued generic competition in the U.S.
- PONVORY® net product sales were $6.8 million in the first quarter of 2024. The acquisition of PONVORY® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company, was completed on December 7, 2023.
- Net loss was $4.1 million in the first quarter of 2024, compared to net income of $3.3 million in the first quarter of 2023, and net loss of $2.4 million in the fourth quarter of 2023.
- Cash, cash equivalents and marketable securities (Cash) was $394.1 million as of March 31, 2024, representing an increase to Cash of $5.9 million compared to December 31, 2023.

Key Operational Highlights

Psychiatry Portfolio

- Fanapt® (iloperidone): Vanda announced in April 2024 that the U.S. Food and Drug Administration (FDA) approved Fanapt® as a first line treatment of acute bipolar I disorder in adults. This approval of Fanapt® for acute bipolar I disorder significantly expands the addressable patient population. Patent exclusivity is expected to last at least through late 2027. Vanda is initiating a host of commercial activities, including the expansion of its existing sales force, a prescriber awareness program and a comprehensive marketing program.
- Milsaperidone: Vanda expects to submit a New Drug Application (NDA) for milsaperidone (also known as VHX-896 and P-88), the active metabolite of Fanapt®, in schizophrenia and acute bipolar I disorder to the FDA in early-2025. If approved, there are pending patent applications that, if issued, could extend exclusivity into the 2040s.
- Fanapt® LAI: Vanda expects to initiate a Phase III program for the long acting injectable (LAI) formulation of Fanapt® by the end of 2024. Fanapt® LAI could reach the U.S. market after 2026 and there are pending patent applications that, if issued, could extend exclusivity into the 2040s.
- Vanda is currently planning clinical programs to test the efficacy of Fanapt® and milsaperidone in the treatment of depressive symptoms which, if successful, will significantly expand the addressable patient population.

HETLIOZ® (tasimelteon)

- Vanda is currently planning to initiate a HETLIOZ LQ® program in pediatric insomnia. Although exact estimates of prevalence of insomnia in children are difficult to quantify, it is estimated that 20-40% of children experience significant sleep problems.[1,2] There are currently no approved treatments for pediatric insomnia. If ultimately approved for marketing, the addressable patient population for HETLIOZ LQ® would be significantly expanded and market exclusivity would be expected to last into the 2040s.
- Vanda announced in March 2024 that it received a complete response letter (CRL) from the FDA related to the supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of insomnia. Vanda is reviewing the CRL and evaluating its next steps. In addition to insomnia, Vanda continues to pursue FDA approval of HETLIOZ® in the treatment of jet lag disorder where the final agency rejection of our application is being challenged in the U.S. Court of Appeals for the D.C. Circuit.
- Vanda announced in April 2024 that the U.S. Supreme Court denied its petition for a writ of certiorari to review the decision of the U.S. Court of Appeals for the Federal Circuit in Vanda's HETLIOZ® Abbreviated New Drug Application litigation against Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. and Apotex Corp (together, Apotex). The lower court decision held that certain claims of Vanda's U.S. Patent Nos. RE46,604; 9,730,910; 10,149,829; and 10,376,487 were invalid. Vanda's suit asserting U.S. Patent No. 11,285,129 will be infringed by Teva's and Apotex's generic versions of HETLIOZ® is currently pending in the U.S. District Court for the District of Delaware.

PONVORY® (ponesimod)

- Vanda expects to complete the transition of PONVORY® from Janssen and commercially launch the product for multiple sclerosis in the third quarter of 2024. Vanda is initiating a host of commercial activities including the creation of a specialty sales force, a prescriber awareness program and a comprehensive marketing program. Currently approved as a once-a-day oral treatment for people with multiple sclerosis, PONVORY® has a differentiated profile from other drugs in the class with high specificity and rapid reversibility, making for a versatile use to address the needs of people with multiple sclerosis and exclusivity is expected to last into the 2040s.
- Positive results from a Phase II clinical study for PONVORY® in the treatment of psoriasis were previously published in Lancet where PONVORY® demonstrated significant effects in both induction and maintenance of response.[3] Vanda expects to file an Investigational New Drug (IND) application with the FDA for PONVORY® in the treatment of psoriasis. Vanda expects to initiate a Phase III study for PONVORY® in the treatment of psoriasis by the end of 2024. If ultimately approved for marketing, PONVORY® would be the first oral sphingosine-1-phosphate (S1P) analog approved for the treatment of psoriasis and would significantly expand the addressable patient population of PONVORY®, with over 8 million people diagnosed with psoriasis in the U.S.[4]
- Vanda expects to file an IND application with the FDA for PONVORY® in the treatment of ulcerative colitis. Vanda expects to initiate a Phase III study for PONVORY® in the treatment of ulcerative colitis by the end of 2024. If

ultimately approved for marketing, PONVORY® would follow other oral sphingosine-1-phosphate (S1P) analogs approved for the treatment of ulcerative colitis and would significantly expand the addressable patient population of PONVORY®, with an estimated prevalence in the U.S. of approximately 2 million individuals.[5]

Tradipitant

- The NDA for tradipitant for the treatment of symptoms of gastroparesis is under review by the FDA with a PDUFA target action date of September 18, 2024. Gastroparesis is a significant unmet medical need with the last treatment option approved over 40 years ago and an estimated prevalence in the U.S. of over 6 million individuals.[6]
- The second Phase III clinical study of tradipitant in the treatment of motion sickness is fully enrolled and results are expected in the second quarter of 2024. The efficacy of tradipitant in the treatment of motion sickness has previously been demonstrated in two clinical studies in which tradipitant was effective in preventing vomiting associated with motion. Vanda expects to submit an NDA for the treatment of motion sickness to the FDA in the fourth quarter of 2024. An eventual NDA approval of tradipitant in the treatment of motion sickness would significantly expand the addressable patient population, with approximately 30% of the U.S. population reported to suffer from motion sickness under ordinary travel conditions that include sea, air and land.[7]

Early-Stage Programs

- The Phase II study of VSJ-110 for the treatment of dry eye is ongoing and more than 50% enrolled.
- The Phase I clinical study for VCA-894A in the treatment of a patient with Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), an inherited peripheral neuropathy for which there is no available treatment, expects to enroll the patient in mid-2024.
- The Phase I clinical study of VTR-297 for the treatment of onychomycosis, a fungal infection of the nail, was initiated in April 2024.
- VQW-765, an alpha-7 nicotinic acetylcholine receptor partial agonist, is currently in clinical development for treatment of acute performance anxiety in social situations.

GAAP Financial Results

Net loss was $4.1 million in the first quarter of 2024 compared to net income of $3.3 million in the first quarter of 2023. Diluted net loss per share was $0.07 in the first quarter of 2024 compared to diluted net income per share of $0.06 in the first quarter of 2023.

2024 Financial Guidance

Given continuing uncertainties surrounding the U.S. market for HETLIOZ® for the treatment of Non-24 as a result of continued generic competition in the U.S. and the upcoming commercial launches for Fanapt® in acute bipolar I disorder and PONVORY® in multiple sclerosis, Vanda is unable to provide 2024 financial guidance at this time.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, May 8, 2024, at 4:30 PM ET. During the call, Vanda's management will discuss the first quarter 2024 financial results and other corporate activities. Investors can call 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and use passcode number 2594340. A replay of the call will be available on Wednesday, May 8, 2024, beginning at 8:30 PM ET and will be accessible until Wednesday, May 15, 2024 at 11:59 PM ET. The replay call-in number is 1-800-770-2030 for domestic callers and 1-609-800-9909 for international callers. The passcode number is 2594340.

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.

References

1. Calhoun SL, Fernandez-Mendoza J, Vgontzas AN, Liao D, Bixler EO. Prevalence of insomnia symptoms in a general population sample of young children and preadolescents: gender effects. Sleep Med. 2014 Jan;15(1):91-5. doi: 10.1016/j.sleep.2013.08.787. Epub 2013 Oct 16. PMID: 24333223; PMCID: PMC3912735.
2. Fricke-Oerkermann L, Plück J, Schredl M, Heinz K, Mitschke A, Wiater A, Lehmkuhl G. Prevalence and course of sleep problems in childhood. Sleep. 2007 Oct;30(10):1371-7. doi: 10.1093/sleep/30.10.1371. PMID: 17969471; PMCID: PMC2266270.
3. Vaclavkova A, Chimenti S, Arenberger P, Holló P, Sator PG, Burcklen M, Stefani M, D'Ambrosio D. Oral ponesimod in patients with chronic plaque psoriasis: a randomised, double-blind, placebo-controlled phase 2 trial. Lancet. 2014 Dec 6;384(9959):2036-45. doi: 10.1016/S0140-6736(14)60803-5. Epub 2014 Aug 10. PMID: 25127208.
4. Datamonitor Healthcare – Psoriasis Patient-Based Market Forecast published March 2023.
5. Datamonitor Healthcare – Ulcerative Colitis Patient-Based Market Forecast published March 2023.
6. Rey et al J Neurogastroenterol Motil, Jan 2012.
7. Turner M, Griffin MJ. Motion sickness in public road transport: passenger behavior and susceptibility. Ergonomics. 1999: 42: 444-461.

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 X @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, statements regarding the advancement of Vanda's clinical development pipeline and strengthening of its commercial presence, Vanda's plans for pursuit of FDA approval of tradipitant in the treatment of symptoms of gastroparesis and the treatment of motion sickness, HETLIOZ® in the treatments of insomnia and jet lag disorder, Vanda's expectations regarding the timing of the FDA's decisions with respect to the sNDAs for HETLIOZ® and the NDA for tradipitant, Vanda's plans for a LAI formulation of Fanapt®, the timing of a submission of an NDA for milsaperidone, the potential for PONVORY® to treat psoriasis and ulcerative colitis, the planned patient enrollment for a clinical study for VCA-894A, the planned launch of PONVORY® in the US and the ongoing launch of Fanapt® in acute bipolar I disorder, the planned clinical programs to test Fanapt® and milsaperidone in depressive symptoms and the planned Hetlioz LQ® program in pediatric insomnia 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 ability to complete the clinical development of the products in its pipeline and obtain regulatory approval and market acceptance of these products, Vanda's ability to obtain FDA approval of the sNDAs for HETLIOZ® and the NDA for tradipitant, the FDA's ability to meet the PDUFA target action date for the NDA for tradipitant, the FDA's assessment of the sufficiency of the data packages included in Vanda's regulatory submissions for HETLIOZ® and tradipitant, Vanda's ability to obtain approval for milsaperidone in the treatment of schizophrenia and acute bipolar I disorder, the results of any clinical trials conducted for PONVORY® in the treatment of other inflammatory/autoimmune disorders, Vanda's ability to obtain regulatory approval of HETLIOZ® and PONVORY® for any additional indications, Vanda's ability to complete the clinical program for tradipitant in the treatment of motion sickness, the planned clinical programs to test Fanapt® and milsaperidone in depressive symptoms and Vanda's ability to execute the planned launch of PONVORY® in the US and ongoing launch of Fanapt®. 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 most recent Annual Report on Form 10-K, 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 2024	**March 31 2023**
Revenues:		
Fanapt® net product sales	$ 20,579	$ 22,882
HETLIOZ® net product sales	20,053	39,616
PONVORY® net product sales	6,830	—
Total revenues	47,462	62,498
Operating expenses:		
Cost of goods sold excluding amortization	3,440	4,774
Research and development	21,154	19,237
Selling, general and administrative	30,085	36,104
Intangible asset amortization	2,018	379
Total operating expenses	56,697	60,494
Income (loss) from operations	(9,235)	2,004
Other income	4,571	3,524
Income (loss) before income taxes	(4,664)	5,528
Provision (benefit) for income taxes	(518)	2,276
Net income (loss)	$ (4,146)	$ 3,252
Net income (loss) per share, basic	$ (0.07)	$ 0.06
Net income (loss) per share, diluted	$ (0.07)	$ 0.06
Weighted average shares outstanding, basic	57,760,940	57,011,396
Weighted average shares outstanding, diluted	57,760,940	57,400,152

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

	March 31 2024	December 31 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 125,158	$ 135,821
Marketable securities	268,984	252,443
Accounts receivable, net	36,713	34,155
Inventory	1,505	1,357
Prepaid expenses and other current assets	7,065	9,170
Total current assets	439,425	432,946
Property and equipment, net	2,306	2,037
Operating lease right-of-use assets	6,742	7,103
Intangible assets, net	119,351	121,369
Deferred tax assets	75,341	75,000
Non-current inventory and other	9,517	9,985
Total assets	$ 652,682	$ 648,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 37,773	$ 38,460
Product revenue allowances	55,569	49,237
Total current liabilities	93,342	87,697
Operating lease non-current liabilities	6,514	7,006
Other non-current liabilities	8,831	8,827
Total liabilities	108,687	103,530
Stockholders' equity:		
Common stock	58	58
Additional paid-in capital	703,858	700,274
Accumulated other comprehensive loss	(383)	(30)
Accumulated deficit	(159,538)	(155,392)
Total stockholders' equity	543,995	544,910
Total liabilities and stockholders' equity	$ 652,682	$ 648,440

Corporate Contact:

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