Vanda Pharmaceuticals Reports First Quarter 2025 Financial Results

May 7, 2025

- *Fanapt® Q1 2025 total prescriptions (TRx) increased 14% compared to Q1 2024*
- *Fanapt® Q1 2025 new to brand prescriptions (NBRx) increased nearly threefold compared to Q1 2024*
- *Bysanti™ (milsaperidone) NDA for bipolar I disorder and schizophrenia accepted for filing; PDUFA target action date of February 21, 2026*
- *Tradipitant NDA for motion sickness accepted for filing; PDUFA target action date of December 30, 2025*
- *Imsidolimab BLA in generalized pustular psoriasis expected to be submitted in 2025*

WASHINGTON, May 7, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the first quarter ended March 31, 2025.

"Vanda has entered a new growth phase with multiple commercialized products and a rich innovative pipeline. Fanapt commercial growth has accelerated, reaching multi-year highs, with weekly prescriptions surpassing 2,000 at the end of April as an increasing number of prescribers are adding Fanapt to their therapeutic armamentarium," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "Our recent new drug application filings for tradipitant and Bysanti are a testament to our productive research and development pipeline. The addition of imsidolimab alongside Ponvory establishes an anti-inflammatory franchise that we believe has significant growth potential. These accomplishments have been possible because of our talented employees, who for the first time surpassed 400 in number, a 22-year high."

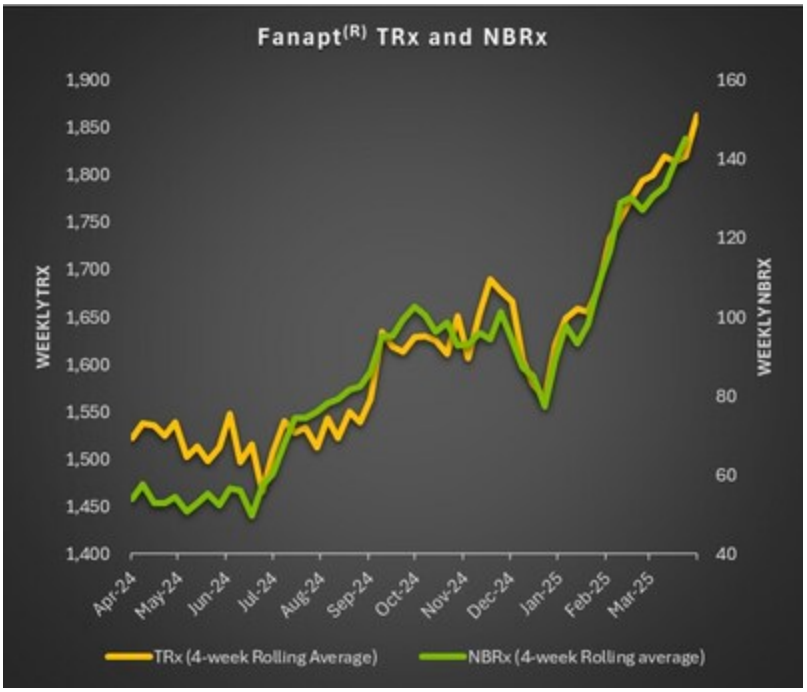
Financial Highlights

- Total net product sales from Fanapt®, HETLIOZ® and PONVORY® were $50.0 million in the first quarter of 2025, a 5% increase compared to $47.5 million in the first quarter of 2024.
- Fanapt® net product sales were $23.5 million in the first quarter of 2025, a 14% increase compared to $20.6 million in the first quarter of 2024.
- HETLIOZ® net product sales were $20.9 million in the first quarter of 2025, a 4% increase compared to $20.1 million in the first quarter of 2024.
- PONVORY® net product sales were $5.6 million in the first quarter of 2025, a decrease of 18% compared to $6.8 million in the first quarter of 2024.
- Net loss was $29.5 million in the first quarter of 2025 compared to net loss of $4.1 million in the first quarter of 2024. The net loss in the first quarter of 2025 reflects expenses associated with the payment of $15.0 million related to the exclusive, global license agreement with AnaptysBio, Inc. (Anaptys) for the development and commercialization of imsidolimab and increased commercial activities.
- Cash, cash equivalents and marketable securities (Cash) was $340.9 million as of March 31, 2025, representing a decrease to Cash of $33.7 million compared to December 31, 2024. The decrease to Cash reflects the payment of $15.0 million during the first quarter of 2025 related to the exclusive, global license agreement with Anaptys for the development and commercialization of imsidolimab.

Key Operational Highlights – Commercial

Fanapt® (iloperidone)

- Fanapt® was approved in the second quarter of 2024 for the acute treatment of bipolar I disorder. Vanda initiated the commercial launch of Fanapt® in this indication in the third quarter of 2024. In the first quarter of 2025, as compared to the first quarter of 2024, total prescriptions (TRx)[1] increased by approximately 14% and Fanapt® net product sales increased by 14%. Additionally, new patient starts, as reflected by new to brand prescriptions (NBRx),[1] increased by nearly threefold in the same period.



- Fanapt® total prescriptions (TRx) for the week of April 25, 2025 reached the milestone of 2,000, making Fanapt® one of the fastest growing atypical antipsychotics.[1] Vanda has also announced an expansion of its psychiatry sales force to approximately 300 representatives.

HETLIOZ® (tasimelteon)

- Through the first quarter of 2025, HETLIOZ® continues to retain the largest portion of market share despite generic competition for over two years.[2]

PONVORY® (ponesimod)

- Vanda initiated the commercial launch of PONVORY® for the treatment of relapsing forms of multiple sclerosis in the third quarter of 2024. In April 2025, new patient prescriptions reached a new record high since the initiation of Vanda's commercial launch. Vanda has re-enforced the PONVORY® sales leadership team and announced an expansion of its PONVORY® sales force to approximately 40 representatives.

Key Operational Highlights – Regulatory & Clinical Development

Key Regulatory Milestones

- Tradipitant New Drug Application (NDA) for motion sickness accepted for filing by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of December 30, 2025.
- Fanapt® Marketing Authorization Application (MAA) for bipolar I disorder and schizophrenia submitted to the European Medicines Agency (EMA) in Q4 2024.
- HETLIOZ® MAA in Smith-Magenis syndrome (SMS) submitted to the EMA in Q4 2024.
- Bysanti™ NDA for bipolar I disorder and schizophrenia accepted for filing by the FDA with a PDUFA target action date of February 21, 2026.
- Imsidolimab Biologics License Application (BLA) in generalized pustular psoriasis (GPP) expected to be submitted to the FDA in 2025.

Key Clinical Highlights

Fanapt® (iloperidone)

- Schizophrenia: A Phase III program for the long acting injectable (LAI) formulation of Fanapt® in the treatment of schizophrenia in relapse prevention is ongoing.
- Hypertension: Vanda initiated a study of the Fanapt® LAI as a once-a-month injectable for uncontrolled hypertension and plans to begin enrolling patients soon.

Bysanti™ (milsaperidone)

- The NDA for Bysanti™ for the acute treatment of bipolar I disorder and the treatment of schizophrenia was accepted for filing by the FDA with a PDUFA target action date of February 21, 2026. Exclusivity for Bysanti™, including pending patent applications, could extend into the 2040s.
- Bysanti™ is a new chemical entity, which was initially identified as an active metabolite of iloperidone. Vanda discovered that milsaperidone, when administered orally, quickly interconverts to iloperidone. In clinical studies, milsaperidone and iloperidone have been shown to be bioequivalent at both low and high doses, administered both in single and multiple dose studies. The results of these clinical studies will be presented in late May, at the 2025 American Society of Clinical Psychopharmacology annual meeting in Scottsdale, Arizona.

- The Bysanti™ Phase III clinical study for use as a once-daily adjunctive treatment for major depressive disorder (MDD) is ongoing. Results are expected in 2026.

HETLIOZ® (tasimelteon)

- HETLIOZ® clinical programs in pediatric insomnia and delayed sleep phase disorder (DSPD) are ongoing.
- Vanda's MAA for HETLIOZ® and HETLIOZ LQ® for SMS is pending with the EMA.

PONVORY® (ponesimod)

- Investigational New Drug (IND) applications for PONVORY® in the treatments of psoriasis and ulcerative colitis were accepted by the FDA in the fourth quarter of 2024.

Tradipitant

- The NDA for tradipitant for the treatment of motion sickness was accepted for filing by the FDA with a PDUFA target action date of December 30, 2025.
- In the fourth quarter of 2024, Vanda initiated a clinical trial to study tradipitant in the prevention of vomiting induced by a GLP-1 analog, Wegovy (semaglutide). Results are expected in the third quarter of 2025.

Imsidolimab

- In February 2025, Vanda announced it entered into an exclusive, global license agreement with Anaptys for the development and commercialization of imsidolimab (IL-36R antagonist mAb). A BLA for GPP is expected to be submitted to the FDA in 2025.

Early-Stage Program Highlights

- VQW-765, an alpha-7 nicotinic acetylcholine receptor partial agonist, is currently in clinical development for the treatment of acute performance anxiety in social situations. Vanda expects to initiate the Phase III program in 2025.
- The IND application for VCA-894A in the treatment of Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), an inherited peripheral neuropathy for which there is no available treatment, was accepted by the FDA in 2024. Previously in 2023, VCA-894A was granted Orphan Drug Designation for the same indication. The Phase I clinical study for VCA-894A expects to enroll the patient by mid-2025.

GAAP Financial Results

Net loss was $29.5 million in the first quarter of 2025 compared to net loss of $4.1 million in the first quarter of 2024. Diluted net loss per share was $0.50 in the first quarter of 2025 compared to diluted net loss per share of $0.07 in the first quarter of 2024.

2025 Financial Guidance

Vanda is reiterating its 2025 total revenues guidance and updating its 2025 financial guidance to include year-end 2025 Cash. Vanda expects to achieve the following financial objectives in 2025:

Full Year 2025 Financial Objectives	Full Year 2025 Guidance
Total revenues	$210 to $250 million
Year-end 2025 Cash	$280 to $320 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, May 7, 2025, at 4:30 PM ET. During the call, Vanda's management will discuss the first quarter 2025 financial results and other corporate activities. Investors can call 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and use passcode number 9941754. A replay of the call will be available on Wednesday, May 7, 2025, beginning at 8:30 PM ET and will be accessible until Wednesday, May 14, 2025 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 9941754.

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. IQVIA Prescription Data
2. Based on blended data analysis

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, the guidance provided under "2025 Financial Guidance" above and statements regarding the growth potential of Vanda's anti-inflammatory franchise; Vanda's plans for pursuit of FDA approval of Bysanti™ for the acute treatment of bipolar I disorder and the treatment of schizophrenia, tradipitant for the treatment of motion sickness, and imsidolimab for the treatment of GPP, and the related timelines; Vanda's plans for pursuit of EMA approval of Fanapt® for the treatment of bipolar I disorder and schizophrenia and HETLIOZ® and HETLIOZ LQ® for the treatment of SMS; Vanda's clinical development plans and expected timelines for Fanapt® LAI as a once-a-month injectable for uncontrolled hypertension, Bysanti™ for the treatment of MDD, VQW-765 for the treatment of acute performance anxiety in social situations, and VCA-894A for the treatment of CMT2S; the expected timing of the results of the tradipitant clinical trial for the prevention of vomiting induced by Wegovy; and the potential to extend patent exclusivity for Bysanti™ into the 2040s 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 continue to grow its business; Vanda's ability to obtain regulatory approval and execute a successful commercial launch of imsidolimab, and increase PONVORY® revenue; the FDA's ability to complete its reviews of, and reach decisions with respect to, the NDAs for Bysanti™ and tradipitant by their respective PDUFA target action dates; Vanda's ability to complete and submit the BLA for imsidolimab in 2025; Vanda's ability to obtain EMA approval of the MAAs for Fanapt® and HETLIOZ® and HETLIOZ LQ®, Vanda's ability to begin enrolling patients in the Fanapt® LAI study within the specified timeframe; Vanda's ability to complete the Phase III clinical study for Bysanti ™for MDD and receive results in 2026; Vanda's ability to complete the clinical trial of tradipitant for the prevention of vomiting induced by Wegovy and receive results in the third quarter of 2025; Vanda's ability to initiate the Phase III program for VQW-765 in 2025; Vanda's ability to enroll the CMT2S patient in the Phase I clinical study for VCA-894A by mid-2025; and Vanda's ability to satisfy the conditions necessary to extend Bysanti™'s patent exclusivity into the 2040s. 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 2025	**March 31 2024**
Revenues:		
Fanapt® net product sales	$ 23,545	$ 20,579
HETLIOZ® net product sales	20,872	20,053
PONVORY® net product sales	5,624	6,830
Total revenues	50,041	47,462
Operating expenses:		
Cost of goods sold excluding amortization	3,521	3,440
Research and development	35,712	21,154
Selling, general and administrative	50,084	30,085
Intangible asset amortization	1,752	2,018
Total operating expenses	91,069	56,697
Loss from operations	(41,028)	(9,235)
Other income, net	3,660	4,571
Loss before income taxes	(37,368)	(4,664)
Benefit for income taxes	(7,874)	(518)
Net loss	$ (29,494)	$ (4,146)
Net loss per share, basic	$ (0.50)	$ (0.07)
Net loss per share, diluted	$ (0.50)	$ (0.07)
Weighted average shares outstanding, basic	58,527,775	57,760,940
Weighted average shares outstanding, diluted	58,527,775	57,760,940

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)
(unaudited)

	March 31 2025	December 31 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,796	$ 102,316
Marketable securities	229,112	272,327
Accounts receivable, net	44,603	47,101
Inventory	1,923	1,726
Prepaid expenses and other current assets	20,476	15,420
Total current assets	407,910	438,890
Property and equipment, net	2,439	2,132
Operating lease right-of-use assets	5,208	5,602
Finance lease right-of-use assets	4,828	4,943
Intangible assets, net	112,344	114,096
Deferred tax assets	89,147	81,440
Non-current inventory and other	10,060	9,101
Total assets	$ 631,936	$ 656,204
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 45,279	$ 39,086
Product revenue allowances	58,644	60,895
Total current liabilities	103,923	99,981
Operating lease non-current liabilities	4,404	4,944
Finance lease non-current liabilities	2,947	3,146
Other non-current liabilities	9,245	9,587
Total liabilities	120,519	117,658
Stockholders' equity:		
Common stock	59	58
Additional paid-in capital	714,761	712,706
Accumulated other comprehensive income	383	74
Accumulated deficit	(203,786)	(174,292)
Total stockholders' equity	511,417	538,546
Total liabilities and stockholders' equity	$ 631,936	$ 656,204

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