



Vanda Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results

February 13, 2025

- Q4 2024 total revenues of \$53.2 million, +17% compared to Q4 2023
 - Q4 2024 Fanapt[®] net product sales of \$26.6 million, +18% compared to Q4 2023
 - Full year 2024 total revenues of \$198.8 million, +3% compared to full year 2023
 - Full year 2025 revenue expected to grow to \$210 to \$250 million
 - Psychiatry portfolio revenue expected to grow to greater than \$750 million in 2030
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- Fanapt[®] MAA for bipolar I disorder and schizophrenia submitted in Q4 2024
 - Bysanti[™] (milsaperidone) NDA for bipolar I disorder and schizophrenia expected to be submitted in Q1 2025
 - HETLIOZ[®] MAA for Smith-Magenis syndrome submitted in Q4 2024
 - Tradipitant NDA for motion sickness submitted in Q4 2024
 - Imsidolimab BLA in generalized pustular psoriasis expected to be submitted in 2025

WASHINGTON, Feb. 13, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the fourth quarter and full year ended December 31, 2024.

"Strong revenue growth for Fanapt is putting us on a significant growth trajectory for 2025 and beyond, supported also by the commercial performance of HetlioZ and Ponvory. The Fanapt long acting injectable program, the NDA for Bysanti for bipolar disorder and schizophrenia along with its development for major depressive disorder have the potential to drive future growth in our psychiatry portfolio for many years to come," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "Tradipitant's NDA for motion sickness was filed with a potential approval this year, while we are pursuing approval in gastroparesis and the development of tradipitant to improve tolerability of GLP-1 analog Wegovy. Our anti-inflammatory portfolio, anchored by Ponvory, was strengthened with the addition of imsidolimab from Anaptys, an IL-36 receptor inhibitor for the treatment of generalized pustular psoriasis. We plan to file a BLA later this year while we are exploring registration in Europe and Japan as well as the development of this novel drug for other inflammatory disorders with an unopposed action of the IL-36 system. In 2024 we returned to revenue growth driven by the commercial launches in bipolar disorder and multiple sclerosis and advanced our development pipeline with a number of products at or near marketing applications. All this was achieved by the hard work, ingenuity and efficiency of our organization and its wonderful people."

Financial Highlights

Fourth Quarter of 2024

- Total net product sales from Fanapt[®], HETLIOZ[®] and PONVORY[®] were \$53.2 million in the fourth quarter of 2024, a 17% increase compared to \$45.3 million in the fourth quarter of 2023 and a 12% increase compared to \$47.7 million in the third quarter of 2024.
- Fanapt[®] net product sales were \$26.6 million in the fourth quarter of 2024, an 18% increase compared to \$22.6 million in the fourth quarter of 2023 and an 11% increase compared to \$23.9 million in the third quarter of 2024.
- HETLIOZ[®] net product sales were \$20.0 million in the fourth quarter of 2024, a 5% decrease compared to \$21.1 million in the fourth quarter of 2023 and a 12% increase compared to \$17.9 million in the third quarter of 2024.
- PONVORY[®] net product sales were \$6.5 million in the fourth quarter of 2024, an increase of 11% compared to \$5.9 million in the third 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 \$4.9 million in the fourth quarter of 2024 compared to net loss of \$2.4 million in the fourth quarter of 2023 and net loss of \$5.3 million in the third quarter of 2024.
- Cash, cash equivalents and marketable securities (Cash) was \$374.6 million as of December 31, 2024, representing a decrease to Cash of \$1.6 million compared to September 30, 2024.

Full Year 2024

- Total net product sales from Fanapt[®], HETLIOZ[®] and PONVORY[®] were \$198.8 million for the full year 2024, a 3% increase compared to \$192.6 million for the full year 2023.
- Fanapt[®] net product sales were \$94.3 million for the full year 2024, a 4% increase compared to \$90.9 million for the full year 2023.
- HETLIOZ[®] net product sales were \$76.7 million for the full year 2024, a 23% decrease compared to \$100.2 million for the full year 2023. The decrease relative to the full year 2023 was the result of continued generic competition in the U.S.
- PONVORY[®] net product sales were \$27.8 million for the full year 2024. The acquisition of PONVORY[®] from Janssen was completed on December 7, 2023.
- Net loss was \$18.9 million for the full year 2024, compared to net income of \$2.5 million for the full year 2023.
- Cash was \$374.6 million as of December 31, 2024, representing a decrease to Cash of \$13.6 million compared to December 31, 2023.

Key Operational Highlights

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 fourth quarter of 2024, as compared to the fourth quarter of 2023, new patient starts, as reflected by new to brand prescriptions (NBRx),¹ increased by over 160% and Fanapt® net product sales increased by 18%.

- Vanda initiated a Phase III program for the long acting injectable (LAI) formulation of Fanapt® in the fourth quarter of 2024.
- Vanda plans to initiate a study of the Fanapt® LAI as a once-a-month injectable for the treatment of hypertension to address both treatment resistance and treatment compliance.
- Vanda submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the fourth quarter of 2024 for Fanapt® for bipolar I disorder and schizophrenia.

Bysanti™ (milsaperidone)

- Vanda expects to submit a New Drug Application (NDA) for Bysanti™ to the U.S. Food and Drug Administration (FDA) for the treatments of acute bipolar I disorder and schizophrenia in the first quarter of 2025. Exclusivity, including pending patent applications, could extend into the 2040s.
- Vanda initiated a Phase III clinical study for Bysanti™ as a once-daily adjunctive treatment for major depressive disorder (MDD) in the fourth quarter of 2024. Results are expected in 2026.

HETLIOZ® (tasimelteon)

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

PONVORY® (ponesimod)

- Vanda initiated the commercial launch of PONVORY® for the treatment of relapsing forms of multiple sclerosis in the third quarter of 2024.
- 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 submitted to the FDA 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), in the fourth quarter of 2024.
- Vanda has accepted the opportunity for a hearing with the FDA on the approvability of the NDA for tradipitant for the treatment of symptoms of gastroparesis.

Imsidolimab

- In February 2025, Vanda announced it entered into an exclusive, global license agreement with AnaptysBio, Inc. (Anaptys) for the development and commercialization of imsidolimab (IL-36R antagonist mAb). Vanda expects to initiate and complete the technology transfer activities in 2025 and immediately begin preparing the Biologics License Application (BLA) and MAA for generalized pustular psoriasis (GPP) for the US and EU. The imsidolimab 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 a 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.
- In December 2024, Vanda announced that the FDA has granted Orphan Drug Designation for VGT-1849A, a selective antisense oligonucleotide (ASO)-based JAK2 inhibitor for the treatment of polycythemia vera (PV), a form of a rare hematologic malignancy that is estimated to affect 1 in 2,000 Americans.

Key Regulatory Milestones

- Tradipitant NDA for motion sickness submitted in Q4 2024.
- Fanapt® MAA for bipolar I disorder and schizophrenia submitted in Q4 2024.
- HETLIOZ® MAA in Smith-Magenis syndrome (SMS) submitted in Q4 2024.
- Bysanti™ NDA for bipolar I disorder and schizophrenia expected to be submitted in Q1 2025.
- Imsidolimab BLA in generalized pustular psoriasis expected to be submitted in 2025.

GAAP Financial Results

Net loss was \$4.9 million in the fourth quarter of 2024 compared to net loss of \$2.4 million in the fourth quarter of 2023. Diluted net loss per share was \$0.08 in the fourth quarter of 2024 compared to diluted net loss per share of \$0.04 in the fourth quarter of 2023.

Net loss was \$18.9 million for the full year 2024 compared to net income of \$2.5 million for the full year 2023. Diluted net loss per share was \$0.33 for the full year 2024 compared to diluted net income per share of \$0.04 for the full year 2023.

2025 Financial Guidance and 2030 Revenue Targets

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

Vanda is providing 2030 revenue targets. For the psychiatry portfolio alone, Vanda is targeting annual revenue in excess of \$750 million in 2030, assuming the potential approval of Bysanti™ for the treatments of acute bipolar I disorder and schizophrenia in early 2026, the potential approval of Bysanti™ for the treatment of MDD, and the potential approval of Fanap® LAI. Vanda is also targeting total annual revenue in excess of \$1 billion in 2030.

Conference Call

Vanda has scheduled a conference call for today, Thursday, February 13, 2025, at 4:30 PM ET. During the call, Vanda's management will discuss the fourth quarter and full year 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 2881765. A replay of the call will be available on Thursday, February 13, 2025, beginning at 8:30 PM ET and will be accessible until Thursday, February 20, 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 2881765.

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

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 and 2030 Revenue Targets" above and the related implied growth of Vanda's business, and statements regarding Vanda's plans for pursuit of FDA approval of Bysanti™ for the treatments of acute bipolar I disorder and schizophrenia and imsidolimab for the treatment of GPP, and the related timelines; Vanda's expectations with respect to the growth opportunities for its psychiatry franchise; Vanda's consideration of foreign regulatory approval for imsidolimab and its potential development for other inflammatory disorders; Vanda's clinical development plans and expected timelines for Fanapt® LAI, 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 commercial and therapeutic potential for Bysanti™; the potential to extend patent exclusivity for Bysanti™ into the 2040s; the anticipated timing of the initiation and completion of technology transfer activities and the preparation of regulatory filings in the US and EU for imsidolimab; and the prevalence of PV 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 psychiatry portfolio and overall business; the results of Vanda's review of foreign regulatory opportunities for imsidolimab; Vanda's ability to identify additional indications for imsidolimab; Vanda's ability to complete and submit to the FDA the NDA for Bysanti™ for the treatments of acute bipolar I disorder and schizophrenia in the first quarter of 2025; Vanda's ability to complete and submit the BLA for imsidolimab for the treatment of GPP in 2025; Vanda's ability to complete the Phase III clinical study for Bysanti™ for MDD and receive results in 2026; 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; Vanda's ability to complete the clinical development of, obtain regulatory approval for, and successfully commercialize, Bysanti™ for the treatments of acute bipolar I disorder, schizophrenia and MDD; Vanda's ability to satisfy the conditions necessary to extend Bysanti™'s patent exclusivity into the 2040s; Vanda's ability to initiate and complete the technology transfer activities and prepare the BLA and MAA for imsidolimab in the specified timeframes; and the accuracy of the estimate regarding the prevalence of PV. 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.

(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31 2024	December 31 2023	December 31 2024	December 31 2023
Revenues:				
Fanapt® net product sales	\$ 26,649	\$ 22,599	\$ 94,297	\$ 90,873
HETLIOZ® net product sales	20,044	21,072	76,675	100,167
PONVORY® net product sales	6,492	1,600	27,800	1,600
Total revenues	53,185	45,271	198,772	192,640
Operating expenses:				
Cost of goods sold excluding amortization	2,590	3,460	11,314	14,796
Research and development	19,840	24,339	74,431	76,823
Selling, general and administrative	39,282	23,613	146,414	112,883
Intangible asset amortization	1,752	953	7,273	2,090
Total operating expenses	63,464	52,365	239,432	206,592
Loss from operations	(10,279)	(7,094)	(40,660)	(13,952)
Other income, net	3,782	5,433	17,739	20,291
Income (loss) before income taxes	(6,497)	(1,661)	(22,921)	6,339
Provision (benefit) for income taxes	(1,585)	739	(4,021)	3,830
Net income (loss)	\$ (4,912)	\$ (2,400)	\$ (18,900)	\$ 2,509
Net income (loss) per share, basic	\$ (0.08)	\$ (0.04)	\$ (0.33)	\$ 0.04
Net income (loss) per share, diluted	\$ (0.08)	\$ (0.04)	\$ (0.33)	\$ 0.04
Weighted average shares outstanding, basic	58,308,487	57,532,309	58,149,087	57,380,975
Weighted average shares outstanding, diluted	58,308,487	57,532,309	58,149,087	57,557,911

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

	December 31 2024	December 31 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 102,316	\$ 135,821
Marketable securities	272,327	252,443
Accounts receivable, net	47,101	34,155
Inventory	1,726	1,357
Prepaid expenses and other current assets	15,420	9,170
Total current assets	438,890	432,946
Property and equipment, net	2,132	2,037
Operating lease right-of-use assets	5,602	7,103
Finance lease right-of-use assets	4,943	—
Intangible assets, net	114,096	121,369
Deferred tax assets	81,440	75,000
Non-current inventory and other	9,101	9,985
Total assets	\$ 656,204	\$ 648,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 39,086	\$ 38,460
Product revenue allowances	60,895	49,237
Total current liabilities	99,981	87,697
Operating lease non-current liabilities	4,944	7,006
Finance lease non-current liabilities	3,146	—
Other non-current liabilities	9,587	8,827
Total liabilities	117,658	103,530
Stockholders' equity:		
Common stock	58	58

Additional paid-in capital	712,706	700,274
Accumulated other comprehensive income (loss)	74	(30)
Accumulated deficit	(174,292)	(155,392)
Total stockholders' equity	<u>538,546</u>	<u>544,910</u>
Total liabilities and stockholders' equity	<u>\$ 656,204</u>	<u>\$ 648,440</u>

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