Vanda Pharmaceuticals Reports Second Quarter 2025 Financial Results

July 31, 2025

- *Fanapt® Q2 2025 net product sales increased by 27% to $29.3 million compared to Q2 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, July 31, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2025.

"We have witnessed accelerated growth of Fanapt revenue coinciding with the expansion of our sales efforts alongside a broad direct to consumer brand awareness campaign and we expect this trend to continue in the coming quarters," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "Significant regulatory and clinical milestones are expected in the coming months which have the potential to strengthen our commercial portfolio and advance our deep clinical pipeline."

Financial Highlights

Second Quarter of 2025

- Total net product sales from Fanapt®, HETLIOZ® and PONVORY® were $52.6 million in the second quarter of 2025, a 4% increase compared to $50.5 million in the second quarter of 2024.
- Fanapt® net product sales were $29.3 million in the second quarter of 2025, a 27% increase compared to $23.2 million in the second quarter of 2024.
- HETLIOZ® net product sales were $16.2 million in the second quarter of 2025, a 13% decrease compared to $18.7 million in the second quarter of 2024.
- PONVORY® net product sales were $7.1 million in the second quarter of 2025, an 18% decrease compared to $8.6 million in the second quarter of 2024.
- Net loss was $27.2 million in the second quarter of 2025 compared to net loss of $4.5 million in the second quarter of 2024.
- Cash, cash equivalents and marketable securities (Cash) was $325.6 million as of June 30, 2025, representing a decrease to Cash of $15.4 million compared to March 31, 2025.

First Six Months of 2025

- Total net product sales from Fanapt®, HETLIOZ® and PONVORY® were $102.6 million in the first six months of 2025, a 5% increase compared to $97.9 million in the first six months of 2024.
- Fanapt® net product sales were $52.8 million in the first six months of 2025, a 21% increase compared to $43.7 million in the first six months of 2024.
- HETLIOZ® net product sales were $37.1 million in the first six months of 2025, a 4% decrease compared to $38.8 million in the first six months of 2024.
- PONVORY® net product sales were $12.7 million in the first six months of 2025, an 18% decrease compared to $15.4 million in the first six months of 2024.
- Net loss was $56.7 million in the first six months of 2025 compared to net loss of $8.7 million in the first six months of 2024.
- Cash was $325.6 million as of June 30, 2025, representing a decrease to Cash of $49.1 million compared to December 31, 2024.

Key Operational Highlights – Commercial

- Fanapt® experienced significant growth with total prescriptions (TRx)[1] increasing by approximately 24% and Fanapt® net product sales increasing by 27% in the second quarter of 2025 as compared to the second quarter of 2024.
- A direct to consumer campaign that started in the first quarter of 2025 continued in the second quarter of 2025, elevating brand awareness of the company and the key products Fanapt® and PONVORY®.

Key Operational Highlights – Regulatory & Clinical Development

- Bysanti™ New Drug Application (NDA) for bipolar I disorder and schizophrenia is under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of February 21, 2026.
- Tradipitant NDA for motion sickness is under review by the FDA with a PDUFA target action date of December 30, 2025.
- A Bysanti™ Phase III clinical study for use as a once-daily adjunctive treatment for major depressive disorder (MDD) is enrolling patients and results are expected in 2026.
- Imsidolimab Biologics License Application (BLA) in generalized pustular psoriasis (GPP) expected to be submitted to the FDA in 2025.

GAAP Financial Results

Net loss was $27.2 million in the second quarter of 2025 compared to net loss of $4.5 million in the second quarter of 2024. Diluted net loss per share was $0.46 in the second quarter of 2025 compared to diluted net loss per share of $0.08 in the second quarter of 2024.

Net loss was $56.7 million in the first six months of 2025 compared to net loss of $8.7 million in the first six months of 2024. Diluted net loss per share was $0.96 in the first six months of 2025 compared to diluted net loss per share of $0.15 in the first six months of 2024.

2025 Financial Guidance

Vanda is reiterating its 2025 financial guidance and 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

HHS Request for Information and Vanda Response

On May 14, 2025, the U.S. Department of Health and Human Services (HHS) issued a Request for Information (RFI) entitled "Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again." On July 14, 2025, Vanda submitted a public response to the RFI. Vanda's response proposed (1) that FDA repeal unlawful regulations that delay and overburden the drug approval process, and (2) that FDA repeal its 1990s-era guidance mandating lethal animal testing. The original RFI is available on the Federal Register website, under document number 2025-08384. Our full response with exhibits is available under the documents section of the Vanda website and on regulations.gov, under comment ID AHRQ-2025-0001-0962.

Conference Call

Vanda has scheduled a conference call for today, Thursday, July 31, 2025, at 8:00 AM ET. During the call, Vanda's management will discuss the second 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 9430387. A replay of the call will be available on Thursday, July 31, 2025, beginning at 11:00 AM ET and will be accessible until Thursday, August 7, 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 9430387.

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" above and statements regarding 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 near-term revenue expectations for Fanapt®; the potential commercial availability of Bysanti™ and tradipitant; and Vanda's clinical development plans and expected timelines for Bysanti™ for the treatment of MDD; 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; 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 increase market awareness of Fanapt® for the acute treatment of bipolar I disorder and continue to drive Fanapt® revenue growth; Vanda's ability to obtain FDA approval of Bysanti™ and tradipitant and successfully execute their commercial launches; and Vanda's ability to complete the Phase III clinical study for Bysanti™ for MDD and receive results in 2026. 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		Six Months Ended	
	June 30 2025	June 30 2024	June 30 2025	June 30 2024
Revenues:				
Fanapt® net product sales	$ 29,294	$ 23,150	$ 52,839	$ 43,729
HETLIOZ® net product sales	16,192	18,708	37,064	38,761
PONVORY® net product sales	7,104	8,616	12,728	15,446
Total revenues	52,590	50,474	102,631	97,936
Operating expenses:				
Cost of goods sold excluding amortization	2,736	2,733	6,257	6,173
Research and development	21,990	16,661	57,702	37,815
Selling, general and administrative	64,616	39,474	114,700	69,559
Intangible asset amortization	1,751	1,752	3,503	3,770
Total operating expenses	91,093	60,620	182,162	117,317
Loss from operations	(38,503)	(10,146)	(79,531)	(19,381)
Other income, net	3,616	4,630	7,276	9,201
Loss before income taxes	(34,887)	(5,516)	(72,255)	(10,180)
Benefit for income taxes	(7,680)	(998)	(15,554)	(1,516)
Net loss	$ (27,207)	$ (4,518)	$ (56,701)	$ (8,664)
Net loss per share, basic	$ (0.46)	$ (0.08)	$ (0.96)	$ (0.15)
Net loss per share, diluted	$ (0.46)	$ (0.08)	$ (0.96)	$ (0.15)
Weighted average shares outstanding, basic	58,993,990	58,220,838	58,762,358	57,990,890
Weighted average shares outstanding, diluted	58,993,990	58,220,838	58,762,358	57,990,890

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

	June 30 2025	December 31 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 80,983	$ 102,316
Marketable securities	244,567	272,327
Accounts receivable, net	44,993	47,101
Inventory	2,169	1,726
Prepaid expenses and other current assets	22,209	15,420
Total current assets	394,921	438,890
Property and equipment, net	2,420	2,132
Operating lease right-of-use assets	4,804	5,602
Finance lease right-of-use assets	5,244	4,943
Intangible assets, net	110,593	114,096
Deferred tax assets	97,143	81,440
Non-current inventory and other	9,621	9,101
Total assets	$ 624,746	$ 656,204
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 57,119	$ 39,086
Product revenue allowances	64,370	60,895
Total current liabilities	121,489	99,981
Operating lease non-current liabilities	3,877	4,944
Finance lease non-current liabilities	3,083	3,146
Other non-current liabilities	9,968	9,587

Total liabilities	138,417	117,658
Stockholders' equity:		
Common stock	59	58
Additional paid-in capital	716,867	712,706
Accumulated other comprehensive income	396	74
Accumulated deficit	(230,993)	(174,292)
Total stockholders' equity	486,329	538,546
Total liabilities and stockholders' equity	$ 624,746	$ 656,204

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