



## Vanda Pharmaceuticals Reports Third Quarter 2025 Financial Results

October 29, 2025

- *Fanapt<sup>®</sup> Q3 2025 net product sales increased by 31% to \$31.2 million compared to Q3 2024*
- *Bysanti<sup>™</sup> (milsaperidone) NDA for bipolar I disorder and schizophrenia under review by the FDA; PDUFA target action date of February 21, 2026*
- *Tradipitant NDA for motion sickness under review by the FDA; PDUFA target action date of December 30, 2025*
- *Imsidolimab BLA in generalized pustular psoriasis expected to be submitted in Q4 2025*
- *Vanda announced collaborative framework with the FDA for resolution of certain disputes*
- *Re-review of Vanda's sNDA for HETLIOZ<sup>®</sup> for the treatment of jet lag disorder by January 7, 2026*

WASHINGTON, Oct. 29, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VANDA) today announced financial and operational results for the third quarter ended September 30, 2025.

"This quarter reflects strong commercial execution, with total net product sales reaching \$56.3 million, up 18% year-over-year, led by a 31% increase in Fanapt sales and 35% growth in prescriptions. HETLIOZ continues to deliver stable performance with \$18.0 million in Q3 sales," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "We are particularly encouraged by our advancing pipeline, with multiple near-term regulatory milestones: the tradipitant NDA for motion sickness under FDA review with a PDUFA target action date of December 30, 2025; the Bysanti NDA for bipolar I disorder and schizophrenia also under FDA review with a PDUFA target action date of February 21, 2026; and the anticipated Q4 submission of the imsidolimab BLA for generalized pustular psoriasis. We are also investing strategically in our commercial infrastructure, including increased brand visibility through targeted sponsorships, with the goal of supporting long-term market leadership and future commercial launches. We believe that these milestones, combined with our collaborative framework with the FDA, will position Vanda for sustained growth and expanded therapeutic impact in 2026 and beyond."

### Financial Highlights

#### Third Quarter of 2025

- Total net product sales from Fanapt<sup>®</sup>, HETLIOZ<sup>®</sup> and PONVORY<sup>®</sup> were \$56.3 million in the third quarter of 2025, an 18% increase compared to \$47.7 million in the third quarter of 2024.
- Fanapt<sup>®</sup> net product sales were \$31.2 million in the third quarter of 2025, a 31% increase compared to \$23.9 million in the third quarter of 2024.
- HETLIOZ<sup>®</sup> net product sales were \$18.0 million in the third quarter of 2025, a 1% increase compared to \$17.9 million in the third quarter of 2024.
- PONVORY<sup>®</sup> net product sales were \$7.0 million in the third quarter of 2025, a 20% increase compared to \$5.9 million in the third quarter of 2024.
- Net loss was \$22.6 million in the third quarter of 2025 compared to net loss of \$5.3 million in the third quarter of 2024.
- Cash, cash equivalents and marketable securities (Cash) was \$293.8 million as of September 30, 2025, representing a decrease to Cash of \$31.8 million compared to June 30, 2025.

#### First Nine Months of 2025

- Total net product sales from Fanapt<sup>®</sup>, HETLIOZ<sup>®</sup> and PONVORY<sup>®</sup> were \$158.9 million in the first nine months of 2025, a 9% increase compared to \$145.6 million in the first nine months of 2024.
- Fanapt<sup>®</sup> net product sales were \$84.1 million in the first nine months of 2025, a 24% increase compared to \$67.6 million in the first nine months of 2024.
- HETLIOZ<sup>®</sup> net product sales were \$55.0 million in the first nine months of 2025, a 3% decrease compared to \$56.6 million in the first nine months of 2024.
- PONVORY<sup>®</sup> net product sales were \$19.8 million in the first nine months of 2025, a 7% decrease compared to \$21.3 million in the first nine months of 2024.
- Net loss was \$79.3 million in the first nine months of 2025 compared to net loss of \$14.0 million in the first nine months of 2024.
- Cash was \$293.8 million as of September 30, 2025, representing a decrease to Cash of \$80.9 million compared to December 31, 2024.

### Key Operational Highlights – Commercial

- Fanapt<sup>®</sup> experienced significant growth, with total prescriptions (TRx)<sup>1</sup> increasing by 35% and Fanapt<sup>®</sup> net product sales increasing by 31% in the third quarter of 2025 as compared to the third quarter of 2024.
- During the first nine months of 2025, Vanda's direct-to-consumer campaign, launched in the first quarter, continued to drive meaningful gains in brand awareness for the company and its products, Fanapt<sup>®</sup> and PONVORY<sup>®</sup>. The Company maintained strategic investments in its commercial infrastructure, including increased brand visibility through targeted sponsorships, with the goal of supporting long-term market leadership and future commercial launches.

### Key Operational Highlights – Regulatory & Clinical Development

- A clinical study of tradipitant in the prevention of vomiting induced by a GLP-1 analog, Wegovy® (semaglutide), is now complete. Results are expected in the fourth quarter of 2025.
- On October 1, 2025, Vanda [announced](#) that it had agreed on a collaborative framework with the U.S. Food and Drug Administration (FDA) for the resolution of certain disputes regarding HETLIOZ® (tasimelteon) and tradipitant. Pursuant to the agreement:
  - The FDA will conduct an expedited re-review of the partial clinical hold preventing long term clinical studies of tradipitant for the treatment of motion sickness by November 26, 2025. The FDA will continue its review of Vanda's New Drug Application (NDA) for this indication, with the existing Prescription Drug User Fee Act (PDUFA) target action date of December 30, 2025.
  - The FDA will conduct an expedited re-review of Vanda's supplemental New Drug Application (sNDA) for HETLIOZ® for the treatment of jet lag disorder by January 7, 2026, including consideration of alternative or narrowed indications focusing on the sleep-related aspects of jet lag disorder.
- Bysanti™ NDA for bipolar I disorder and schizophrenia is under review by the FDA with a 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.
- Imisdolimab Biologics License Application (BLA) in generalized pustular psoriasis (GPP) expected to be submitted to the FDA in the fourth quarter of 2025.
- The Phase III study of the long acting injectable formulation of iloperidone in the treatment of schizophrenia in relapse-prevention is enrolling patients.
- A clinical study of the long acting injectable formulation of iloperidone in people with treatment-resistant hypertension is ongoing and Vanda plans to begin enrolling patients soon.

### GAAP Financial Results

Net loss was \$22.6 million in the third quarter of 2025 compared to net loss of \$5.3 million in the third quarter of 2024. Diluted net loss per share was \$0.38 in the third quarter of 2025 compared to diluted net loss per share of \$0.09 in the third quarter of 2024.

Net loss was \$79.3 million in the first nine months of 2025 compared to net loss of \$14.0 million in the first nine months of 2024. Diluted net loss per share was \$1.35 in the first nine months of 2025 compared to diluted net loss per share of \$0.24 in the first nine months of 2024.

### 2025 Financial Guidance

Vanda is updating its 2025 financial guidance and expects to achieve the following financial objectives in 2025:

Full Year 2025 Financial Objectives	Prior Full Year 2025 Guidance	Revised Full Year 2025 Guidance
Total revenues	\$210 to \$250 million	\$210 to \$230 million
Year-end 2025 Cash	\$280 to \$320 million	\$260 to \$290 million

### Conference Call

Vanda has scheduled a conference call for today, Wednesday, October 29, 2025, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 2025 financial results and other corporate activities. Investors can call 1-888-596-4144 (domestic) or 1-646-968-2525 (international) and use passcode number 8728050. A replay of the call will be available on Wednesday, October 29, 2025, beginning at 7:00 PM ET and will be accessible until Wednesday, November 5, 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 8728050.

The conference call will be broadcast simultaneously on Vanda's website, [www.vandapharma.com](http://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](http://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 imisdolimab for the treatment of GPP, and the related timelines and prospects for approval; the goals and expected results of Vanda's commercial infrastructure investment strategy; Vanda's expectations with respect to the strength of its business; Vanda's clinical development plans and expected timelines for tradipitant in the prevention of vomiting induced by Wegovy®, Bysanti™ for the treatment of MDD and the long acting injectable formulation of iloperidone in the treatments of schizophrenia in relapse-prevention and hypertension; and the actions that the FDA is expected to take, and the timing thereof, with respect to the NDA for tradipitant for the treatment of motion sickness and the sNDA for HETLIOZ® for the treatment of jet lag disorder 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 the fourth quarter of 2025; Vanda's ability to achieve long-term market leadership and execute new commercial launches through its commercial infrastructure investments; Vanda's ability to complete the clinical studies for tradipitant in the prevention of vomiting induced by Wegovy® and Bysanti™ for the treatment of MDD and receive results in the expected timeframes; Vanda's ability to complete enrollment of patients in the clinical study for the long acting injectable formulation of iloperidone in the treatment of schizophrenia in relapse-prevention and to begin enrolling patients in the study of the long acting injectable formulation of iloperidone for the treatment of hypertension in the expected timeframe; and the FDA's ability to conduct expedited re-reviews of the partial clinical hold on tradipitant for the treatment of motion sickness by November 26, 2025 and the sNDA for HETLIOZ® for the treatment of jet lag disorder by January 7, 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](http://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		Nine Months Ended	
	September 30 2025	September 30 2024	September 30 2025	September 30 2024
Revenues:				
Fanapt® net product sales	\$ 31,245	\$ 23,919	\$ 84,084	\$ 67,648
HETLIOZ® net product sales	17,978	17,870	55,042	56,631
PONVORY® net product sales	7,035	5,862	19,763	21,308
Total revenues	56,258	47,651	158,889	145,587
Operating expenses:				
Cost of goods sold excluding amortization	2,954	2,551	9,211	8,724
Research and development	22,563	16,776	80,265	54,591
Selling, general and administrative	60,273	37,573	174,973	107,132
Intangible asset amortization	1,752	1,751	5,255	5,521
Total operating expenses	87,542	58,651	269,704	175,968
Loss from operations	(31,284)	(11,000)	(110,815)	(30,381)
Other income, net	2,894	4,756	10,170	13,957
Loss before income taxes	(28,390)	(6,244)	(100,645)	(16,424)
Benefit for income taxes	(5,804)	(920)	(21,358)	(2,436)
Net loss	\$ (22,586)	\$ (5,324)	\$ (79,287)	\$ (13,988)
Net loss per share, basic	\$ (0.38)	\$ (0.09)	\$ (1.35)	\$ (0.24)
Net loss per share, diluted	\$ (0.38)	\$ (0.09)	\$ (1.35)	\$ (0.24)
Weighted average shares outstanding, basic	59,091,478	58,261,961	58,873,268	58,095,566
Weighted average shares outstanding, diluted	59,091,478	58,261,961	58,873,268	58,095,566

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

	September 30 2025	December 31 2024
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 70,022	\$ 102,316
Marketable securities	223,730	272,327
Accounts receivable, net	50,541	47,101

Inventory	2,042	1,726
Prepaid expenses and other current assets	21,161	15,420
Total current assets	367,496	438,890
Property and equipment, net	2,460	2,132
Operating lease right-of-use assets	4,368	5,602
Finance lease right-of-use assets	5,071	4,943
Intangible assets, net	108,841	114,096
Deferred tax assets	103,073	81,440
Non-current inventory and other	9,831	9,101
Total assets	\$ 601,140	\$ 656,204

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Accounts payable and accrued liabilities	\$ 47,619	\$ 39,086
Product revenue allowances	70,251	60,895
Total current liabilities	117,870	99,981
Operating lease non-current liabilities	3,419	4,944
Finance lease non-current liabilities	2,808	3,146
Other non-current liabilities	11,044	9,587
Total liabilities	135,141	117,658

##### Stockholders' equity:

Common stock	59	58
Additional paid-in capital	718,979	712,706
Accumulated other comprehensive income	540	74
Accumulated deficit	(253,579)	(174,292)
Total stockholders' equity	465,999	538,546
Total liabilities and stockholders' equity	\$ 601,140	\$ 656,204

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