Vanda Pharmaceuticals Reports Third Quarter 2026 Financial Results

October 28, 2026

- *Q3 2026 Total Revenues increased 24% to $69.8 million compared to Q3 2025 and 38% compared to Q2 2026*
- *Q3 2026 Total Operating Expenses decreased by 18% to $93.3 million compared to Q2 2026*
- *Announced positive results from the Phase III study of NEREUS™ for prevention of GLP-1-induced vomiting*
- *NEREUS™ for prevention of vomiting induced by motion became commercially available in Q2 2026*
- *BYSANTI™ commercial launch expected in Q4 2026*
- *Quimilza™ BLA for GPP under review by the FDA; PDUFA target action date of December 12, 2026*

WASHINGTON, Oct. 28, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2026.

"We are pleased with the strong revenue growth in the third quarter, increasing 24% year-over-year, driven by continued Fanapt momentum and the early contribution from our NEREUS commercial launch, while operating expenses decreased 18% compared to the second quarter as key Phase III and launch-preparation activities conclude," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "Looking ahead, with the commercial launch of BYSANTI expected in the fourth quarter, the Quimilza BLA under FDA review with a December PDUFA date, and positive Phase III results supporting potential expansions for NEREUS in GLP-1-induced vomiting and HETLIOZ in Delayed Sleep-Wake Phase Disorder, we are focused on further moderating costs and driving revenue growth from our current portfolio and planned launches to support sustainable long-term value."

Financial Highlights

Operating Expenses

- During 2025 and 2026, Vanda has advanced multiple Phase III programs, continued its commercial activities for Fanapt® (iloperidone), HETLIOZ® (tasimelteon) and PONVORY® (ponesimod) and prepared for the commercial launches, including manufacturing commercial supplies, of NEREUS™ (tradipitant), BYSANTI™ (milsaperidone), and Quimilza™ (imsidolimab). These activities resulted in significantl increased operating expenses in 2025 and 2026. As certain of these activities began concluding in Q3 2026, operating expenses have decreased and Vanda expects operating expenses to decrease further in future quarters, as the remainder of these activities conclude.

Third Quarter of 2026

- Total net product sales were $69.8 million in Q3 2026, a 24% increase compared to $56.3 million in Q3 2025 and a 38% increase compared to $50.5 million in Q2 2026. Total net product sales includes approximately $7.0 million of HETLIOZ® revenue for orders shipped on June 29, 2026 that arrived on July 1, 2026.
- Total operating expenses were $93.3 million in Q3 2026, a 7% increase compared to $87.5 million in Q3 2025 and an 18% decrease compared to $114.3 million in Q2 2026.
- Fanapt® net product sales were $38.8 million in Q3 2026, a 24% increase compared to $31.2 million in Q3 2025 and an 8% increase compared to $36.0 million in Q2 2026.
- HETLIOZ® net product sales were $21.7 million in Q3 2026, a 21% increase compared to $18.0 million in Q3 2025 and a 289% increase compared to $5.6 million in Q2 2026, and includes orders totaling approximately $7.0 million in revenue that were shipped on June 29, 2026 and arrived on July 1, 2026. These orders were recognized as revenue in Q3 2026.
- PONVORY® net product sales were $7.7 million in Q3 2026, a 10% increase compared to $7.0 million in Q3 2025 and a 2% decrease compared to $7.9 million in Q2 2026.
- NEREUS™ net product sales were $1.6 million in Q3 2026, a 60% increase compared to $1.0 million in Q2 2026. Vanda launched NEREUS™ commercially in the U.S. in Q2 2026, with the direct-to-consumer offering via the web portal nereus.us, and began sales force promotion in Q3 2026.
- Loss before income taxes was $22.4 million in Q3 2026 compared with $28.4 million in Q3 2025.
- Cash, cash equivalents and marketable securities (Cash) totaled $140.5 million as of September 30, 2026, representing a decrease to Cash of $29.5 million in Q3 2026.

First Nine Months of 2026

- Total net product sales were $172.1 million in the first nine months of 2026, an 8% increase compared to $158.9 million in the first nine months of 2025.
- Total operating expenses were $309.6 million in the first nine months of 2026, a 15% increase compared to $269.7 million in the first nine months of 2025.
- Fanapt® net product sales were $104.3 million in the first nine months of 2026, a 24% increase compared to $84.1 million in the first nine months of 2025.
- HETLIOZ® net product sales were $43.2 million in the first nine months of 2026, a 21% decrease compared to $55.0 million in the first nine months of 2025.
- PONVORY® net product sales were $21.9 million in the first nine months of 2026, an 11% increase compared to $19.8 million in the first nine months of 2025.
- NEREUS™ net product sales were $2.6 million in the first nine months of 2026.

- Loss before income taxes was $133.2 million in the first nine months of 2026 compared with $100.6 million in the first nine months of 2025.
- Cash, cash equivalents and marketable securities (Cash) totaled $140.5 million as of September 30, 2026, representing a decrease to Cash of $123.4 million compared to December 31, 2025.

Key Commercial Highlights

- Fanapt® saw continued strong momentum in Q3 2026, with total prescriptions (TRx)[1] up 25% and new-to-brand prescriptions (NBRx)[1] up 18% versus Q3 2025. Since commercial expansion following the approval of bipolar disorder, Fanapt® has seen significant growth, with TRx[1] up 72% and NBRx[1] up 306% versus Q2 2024.
- BYSANTI™ received U.S. Food and Drug Administration (FDA) approval for the treatment of bipolar I disorder and schizophrenia in Q1 2026 and is expected to launch in Q4 2026. BYSANTI™ is protected by data exclusivity through February 20, 2031 and multiple patents, the latest of which expires on May 31, 2044.
- Vanda launched NEREUS™ commercially in the U.S. in Q2 2026, with the direct-to-consumer offering via the web portal nereus.us, and began sales force promotion in Q3 2026. During Q3 2026, the NEREUS™ launch showed strong growth in both total prescriptions and unique prescribers as compared to Q2 2026.

Key Regulatory & Clinical Development Highlights

Recent & Upcoming Milestones

- In October 2026, Vanda announced positive results from the Phase III clinical study, VP-VLY-686-3601, of NEREUS™ for the prevention of vomiting associated with GLP-1 receptor agonist therapy. Vanda intends to discuss the results with the FDA and plans to submit a supplemental New Drug Application (sNDA) seeking approval of NEREUS™ for the prevention of vomiting associated with GLP-1 receptor agonist therapy.
- In September 2026, Vanda announced positive topline results from the pivotal Phase III study of HETLIOZ® in adults with Delayed Sleep-Wake Phase Disorder (DSWPD). Vanda intends to discuss these data with the FDA and to submit an sNDA seeking approval of HETLIOZ® for DSWPD. If approved, HETLIOZ® would be the first FDA-approved medicine indicated for this condition.
- The Biologics License Application (BLA) for Quimilza™ in Generalized Pustular Psoriasis (GPP) is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of December 12, 2026. The results of the pivotal clinical study were published in the April 28, 2026 issue of the New England Journal of Medicine (NEJM) Evidence[2].
- The Phase III study of BYSANTI™ as a once-daily adjunctive treatment for major depressive disorder (MDD) is ongoing, with results expected in the first half of 2027. The study is enrolling patients in 54 sites in the U.S. and Europe and has enrolled 55% of the 500 patient enrollment target. The primary endpoint of the study is the change from baseline to week 6 of the Montgomery-Asberg Depression Rating Scale (MADRS) comparing milsaperidone and placebo. Secondary endpoints include Clinical Global Impression – Severity (CGI-S) and Clinical Global Impression – Change (CGI-C).

Regulatory Proceedings

- Vanda continues to progress the FDA formal hearing regarding HETLIOZ® for the treatment of jet lag disorder. The proceeding, a rare administrative hearing process granted after the D.C. Circuit set aside the FDA's prior refusal to approve the application, is advancing according to schedule and is expected to culminate in a five-day hearing before the Administrative Law Judge from December 14, 2026 to December 18, 2026.
- Vanda continues to pursue its legal challenge to FDA's final order refusing to hold a hearing or to approve the Company's sNDA for HETLIOZ® in the treatment of insomnia. Following oral argument before the U.S. Court of Appeals for the D.C. Circuit in September 2026, the matter is awaiting decision.
- Vanda continues to pursue its legal challenge to FDA's final order refusing to hold a hearing or to approve the Company's NDA for NEREUS™ in gastroparesis. Briefing is currently underway before the DC Circuit, and is due to be completed in mid-November.

GAAP Financial Results

Net loss was $22.6 million (diluted loss per share of $0.37) in Q3 2026 compared with a net loss of $22.6 million (diluted loss per share of $0.38) in Q3 2025 and a net loss of $62.5 million (diluted net loss per share of $1.04) in Q2 2026.

Net loss was $133.6 million (diluted loss per share of $2.23) in the first nine months of 2026 compared with a net loss of $79.3 million (diluted loss per share of $1.35) in the first nine months of 2025.

2026 Financial Guidance

Vanda is updating its 2026 financial guidance and expects to achieve total revenue for full year 2026 of greater than $240 million.

Conference Call

Vanda has scheduled a conference call for today, Wednesday, October 28, 2026, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 2026 financial results and other corporate activities. Investors can call 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and use passcode number 1178705. A replay of the call will be available on Wednesday, October 28, 2026, beginning at 8:30 PM ET and will be accessible until Wednesday, November 4, 2026 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 1178705.

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. Smieszek, S. *et al.* Efficacy and Safety of Imsidolimab for Generalized Pustular Psoriasis. *NEJM Evidence* **5**, (2026).

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 "2026 Financial Guidance" above and statements regarding the expected timing of the commercial launch of BYSANTI™ for the treatment of bipolar I disorder and schizophrenia; the anticipated timing of the completion of the FDA's review of the Quimilza™ BLA for the treatment of GPP; Vanda's plans and expectations regarding the regulatory path for NEREUS™ for the prevention of vomiting associated with GLP-1 receptor agonist therapy; Vanda's clinical development and regulatory plans and expected timeline for HETLIOZ® in the treatment of DSWPD; Vanda's expectations with respect to its operating expense run rate; Vanda's clinical development plans and expected timeline for BYSANTI™ for the treatment of MDD; Vanda's continued pursuit of FDA approval of HETLIOZ® for the treatment of jet lag disorder and Vanda's expectations with respect to the HETLIOZ® evidentiary hearing; Vanda's continued pursuit of FDA approval of HETLIOZ® for the treatment of insomnia and NEREUS™ for the treatment of gastroparesis; and Vanda's expectations with respect to the strength of its business 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 successfully execute the commercial launch of BYSANTI™ for the treatments of bipolar I disorder and schizophrenia in Q4 2026; Vanda's ability to successfully launch and commercialize its recently approved products and any product that may be approved in the future; Vanda's ability to continue to reduce its operating expenses; the FDA's ability to complete its review of, and reach a decision with respect to, the BLA for Quimilza™ by December 12, 2026; the FDA's willingness to meet with Vanda to discuss the NEREUS™ Phase III clinical study results and Vanda's ability to gain alignment with the FDA on the regulatory path for NEREUS™ and submit an sNDA for NEREUS™ for the prevention of vomiting associated with GLP-1 receptor agonist therapy; the FDA's willingness to meet with Vanda to discuss the HETLIOZ® Phase III clinical study results and Vanda's ability to gain alignment with the FDA on the regulatory path for HETLIOZ® in the treatment of DSWPD and to obtain regulatory approval of HETLIOZ® for this indication; Vanda's ability to meet its enrollment target for, and complete, the Phase III study for BYSANTI™ for the treatment of MDD and receive results in the first half of 2027; and the outcomes of the administrative hearing process for HETLIOZ® for the treatment of jet lag disorder and the court cases for HETLIOZ® for the treatment of insomnia and NEREUS™ for the treatment of gastroparesis. 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		Nine Months Ended	
	September 30 2026	September 30 2025	September 30 2026	September 30 2025
Revenues:				
Fanapt® net product sales	$ 38,765	$ 31,245	$ 104,314	$ 84,084
HETLIOZ® net product sales	21,689	17,978	43,212	55,042
PONVORY® net product sales	7,749	7,035	21,895	19,763
NEREUS™ net product sales	1,612	—	2,641	—
Total revenues	69,815	56,258	172,062	158,889
Operating expenses:				
Cost of goods sold excluding amortization	4,152	2,954	10,871	9,211
Research and development	27,622	22,563	93,010	80,265
Selling, general and administrative	59,575	60,273	199,774	174,973
Intangible asset amortization	1,987	1,752	5,961	5,255
Total operating expenses	93,336	87,542	309,616	269,704
Loss from operations	(23,521)	(31,284)	(137,554)	(110,815)
Other income, net	1,133	2,894	4,358	10,170

Loss before income taxes	(22,388)	(28,390)	(133,196)	(100,645)
Provision (benefit) for income taxes	174	(5,804)	446	(21,358)
Net loss	$ (22,562)	$ (22,586)	$ (133,642)	$ (79,287)
Net loss per share, basic	$ (0.37)	$ (0.38)	$ (2.23)	$ (1.35)
Net loss per share, diluted	$ (0.37)	$ (0.38)	$ (2.23)	$ (1.35)
Weighted average shares outstanding, basic	60,465,170	59,091,478	60,054,252	58,873,268
Weighted average shares outstanding, diluted	60,465,170	59,091,478	60,054,252	58,873,268

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

	September 30 2026	December 31 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,933	$ 84,851
Marketable securities	78,561	178,996
Accounts receivable, net	60,316	54,578
Inventory	1,528	1,852
Prepaid expenses and other current assets	36,129	26,985
Total current assets	238,467	347,262
Property and equipment, net	3,029	2,248
Operating lease right-of-use assets	14,225	3,923
Finance lease right-of-use assets	5,949	7,343
Intangible assets, net	111,128	117,089
Non-current inventory and other	9,529	11,083
Total assets	$ 382,327	$ 488,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 60,588	$ 68,297
Product revenue allowances	94,392	76,865
Total current liabilities	154,980	145,162
Operating lease non-current liabilities	14,949	2,991
Finance lease non-current liabilities	2,345	4,076
Other non-current liabilities	10,195	9,533
Total liabilities	182,469	161,762
Stockholders' equity:		
Common stock	60	59
Additional paid-in capital	728,272	721,264
Accumulated other comprehensive income (loss)	(66)	629
Accumulated deficit	(528,408)	(394,766)
Total stockholders' equity	199,858	327,186
Total liabilities and stockholders' equity	$ 382,327	$ 488,948

Corporate Contact:

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Jim Golden / Jack Kelleher / Dan Moore
Collected Strategies
VANDA-CS@collectedstrategies.com

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