



Vanda Pharmaceuticals Reports Third Quarter 2024 Financial Results

November 6, 2024

- Revenues for Q3 2024 were \$47.7 million, an increase of 23% compared to Q3 2023
- Financial Guidance revised for Full Year 2024, raising the midpoint of revenue and cash ranges
- Fanapt[®] launch in bipolar I disorder; new patient starts increased by over 90% in Q3 2024 as compared to Q3 2023
- Fanapt[®] long acting injectable program expected to be initiated in Q4 2024
- Milsaperidone NDA for schizophrenia and bipolar I disorder expected to be submitted in early 2025; initiation of major depressive disorder program expected in Q4 2024
- PONVORY[®] commercial launch for multiple sclerosis initiated in Q3 2024
- PONVORY[®] IND applications for psoriasis and ulcerative colitis expected to be submitted in Q4 2024
- Tradipitant NDA for motion sickness expected to be submitted in Q4 2024

WASHINGTON, Nov. 6, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the third quarter ended September 30, 2024.

"We are very pleased with the lead indicators of the initial market response to our commercial launch of Fanapt in bipolar I disorder, a testament to the strong clinical evidence and the strength of our commercial strategy, and we look forward to continuous growth in the coming quarters. In parallel, we have launched Ponvory for multiple sclerosis and we are looking forward to increased prescriber and patient awareness in the near future. We expect Fanapt, milsaperidone and Fanapt LAI to form a diverse and expanding psychiatry franchise for years to come," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "On the research and development front, we are focused on completing in the coming months our New Drug Applications for tradipitant in motion sickness and for milsaperidone in schizophrenia and bipolar I disorder. IND filings are expected to be completed for Ponvory in ulcerative colitis and psoriasis later this quarter. We are committed to growing our revenue from our existing products and continuing to diversify our sources of revenue through indication expansion and new product development."

Financial Highlights

Third Quarter of 2024

- Total net product sales from Fanapt[®], HETLIOZ[®] and PONVORY[®] were \$47.7 million in the third quarter of 2024, a 23% increase compared to \$38.8 million in the third quarter of 2023.
- Fanapt[®] net product sales were \$23.9 million in the third quarter of 2024, a 12% increase compared to \$21.3 million in the third quarter of 2023.
- HETLIOZ[®] net product sales were \$17.9 million in the third quarter of 2024, a 2% increase compared to \$17.5 million in the third quarter of 2023.
- PONVORY[®] net product sales were \$5.9 million in the third quarter of 2024, a decrease of 32% compared to \$8.6 million in the second 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 \$5.3 million in the third quarter of 2024 compared to net income of \$0.1 million in the third quarter of 2023.
- Cash, cash equivalents and marketable securities (Cash) was \$376.3 million as of September 30, 2024, representing a decrease to Cash of \$11.4 million compared to June 30, 2024. The Cash balance of \$376.3 million as of September 30, 2024 does not include a payment from Janssen for \$8.1 million primarily related to second quarter 2024 PONVORY[®] revenue receivables, which was received in the fourth quarter of 2024.

First Nine Months of 2024

- Total net product sales from Fanapt[®], HETLIOZ[®] and PONVORY[®] were \$145.6 million in the first nine months of 2024, a 1% decrease compared to \$147.4 million in the first nine months of 2023.
- Fanapt[®] net product sales were \$67.6 million in the first nine months of 2024, a 1% decrease compared to \$68.3 million in the first nine months of 2023.
- HETLIOZ[®] net product sales were \$56.6 million in the first nine months of 2024, a 28% decrease compared to \$79.1 million in the first nine months of 2023. The decrease relative to the first nine months of 2023 was the result of continued generic competition in the U.S.
- PONVORY[®] net product sales were \$21.3 million in the first nine months of 2024. The acquisition of PONVORY[®] from Janssen was completed on December 7, 2023.
- Net loss was \$14.0 million in the first nine months of 2024, compared to net income of \$4.9 million in the first nine months of 2023.
- Cash was \$376.3 million as of September 30, 2024, representing a decrease to Cash of \$12.0 million compared to December 31, 2023. The Cash balance of \$376.3 million as of September 30, 2024 does not include a payment from Janssen for \$8.1 million primarily related to second quarter 2024 PONVORY[®] revenue receivables, which was received in the fourth quarter of 2024.

Key Operational Highlights

Psychiatry Portfolio

- Fanapt[®] (iloperidone): Vanda initiated the commercial launch of Fanapt[®] for the acute treatment of bipolar I disorder in adults in the third quarter of 2024, which included the expansion of its existing sales force and the introduction of prescriber awareness and comprehensive

marketing programs. Several lead indicators suggest a strong initial market response including new patient starts as reflected by new to brand prescriptions (NBRx),¹ increasing by over 90% in the third quarter of 2024 as compared to the third quarter of 2023.

- Milsaperidone: Vanda expects to submit a New Drug Application (NDA) for milsaperidone (also known as VHX-896 and P-88), the active metabolite of Fanapt[®], for the treatments of schizophrenia and acute bipolar I disorder to the U.S. Food and Drug Administration (FDA) in early 2025. Vanda expects to initiate a Phase III program for milsaperidone for major depressive disorder (MDD) by the end of 2024.
- Iloperidone long acting injectable (LAI): Vanda expects to initiate a Phase III program for the LAI formulation of Fanapt[®] in the fourth quarter of 2024.

HETLIOZ[®] (tasimelteon)

- Vanda has initiated a HETLIOZ LQ[®] program in pediatric insomnia. Although the prevalence of insomnia in children is difficult to determine, it is estimated that 20-40% of children experience significant sleep problems.^{2,3} There are currently no approved treatments for pediatric insomnia.
- Vanda continues to pursue FDA approval for HETLIOZ[®] for the treatments of jet lag disorder and insomnia. Vanda is challenging the FDA's rejection of Vanda's supplemental New Drug Application (sNDA) for the treatment of jet lag disorder in the U.S. Court of Appeals for the D.C. Circuit. Vanda has accepted the opportunity for a hearing with the FDA on the approvability of the insomnia sNDA.
- Vanda's litigation asserting HETLIOZ[®] Patent No. 11,285,129 against generic manufacturers is currently pending in the U.S. District Court for the District of Delaware. A jury trial has been scheduled for the first quarter of 2026.
- European Medicines Agency action on Vanda's Marketing Authorization Application for HETLIOZ[®] and HETLIOZ LQ[®] for Smith-Magenis Syndrome is expected in the first quarter of 2025.

PONVORY[®] (ponesimod)

- Vanda initiated the commercial launch of PONVORY[®] for the treatment of relapsing forms of multiple sclerosis in the third quarter of 2024, which included the deployment of a specialty sales force.
- Vanda expects Investigational New Drug (IND) applications for PONVORY[®] in the treatments of psoriasis and ulcerative colitis to be completed in the fourth quarter of 2024.

Tradipitant

- Gastroparesis NDA: In September 2024, the FDA declined to approve Vanda's NDA for tradipitant for the treatment of symptoms of gastroparesis. Vanda plans to continue to pursue the marketing authorization for tradipitant and support the expanded access program that is currently serving several dozen patients with gastroparesis.
- Motion Sickness NDA: Vanda expects to submit an NDA for tradipitant for the treatment of motion sickness to the FDA in the fourth quarter of 2024. The NDA for the treatment of motion sickness is expected to include the positive results of three placebo controlled clinical studies where tradipitant was effective in preventing vomiting associated with motion.
- Vanda plans to initiate a clinical trial to study tradipitant in the prevention of vomiting induced by a GLP-1 analog (semaglutide) in the fourth quarter of 2024.

Early-Stage Programs

- Vanda plans to proceed with studies of VSJ-110, a CFTR activator, for the treatment of dry eye disorder. An ongoing proof of concept study indicates an effect in improving the signs (fluorescein corneal staining) of dry eye disease.
- VPO-227, a CFTR inhibitor for the treatment of cholera, has received approval to proceed in a Phase I study in Bangladesh, a country where the treatment of cholera remains a significant and unmet need. Vanda plans to initiate this study by the end of 2024.
- The Phase I clinical study for VCA-894A for the treatment of a patient with Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), an inherited peripheral neuropathy for which there is no available treatment, expects to enroll the patient by the end of 2024.
- The Phase I clinical study for VTR-297 for the treatment of onychomycosis, a fungal infection of the nail, was initiated in April 2024. The study is fully enrolled, and results are expected by the end of 2024.
- 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.

GAAP Financial Results

Net loss was \$5.3 million in the third quarter of 2024 compared to net income of \$0.1 million in the third quarter of 2023. Diluted net loss per share was \$0.09 in the third quarter of 2024 compared to diluted net income per share of \$0.00 in the third quarter of 2023.

Net loss was \$14.0 million in the first nine months of 2024 compared to net income of \$4.9 million in the first nine months of 2023. Diluted net loss per share was \$0.24 in the first nine months of 2024 compared to diluted net income per share of \$0.09 in the first nine months of 2023.

2024 Financial Guidance

Vanda is updating its 2024 financial guidance and expects to achieve the following financial objectives in 2024:

Full Year 2024 Financial Objectives	Prior Full Year 2024 Guidance	Revised Full Year 2024 Guidance
Total revenues	\$180 to \$210 million	\$190 to \$210 million
Year-end 2024 Cash	\$360 to \$390 million	\$370 to \$390 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, November 6, 2024, at 4:30 PM ET. During the call, Vanda's management will discuss the third quarter 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 2555000. A replay of the call will be available on Wednesday, November 6, 2024, beginning at 8:30 PM ET and will be accessible until Wednesday, November 13, 2024 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 2555000.

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. Calhoun SL, Fernandez-Mendoza J, Vgontzas AN, Liao D, Bixler EO. Prevalence of insomnia symptoms in a general population sample of young children and preadolescents: gender effects. *Sleep Med.* 2014 Jan;15(1):91-5. doi: 10.1016/j.sleep.2013.08.787. Epub 2013 Oct 16. PMID: 24333223; PMCID: PMC3912735.
3. Fricke-Oerkemann L, Plücker J, Schredl M, Heinz K, Mitschke A, Wiater A, Lehmkühl G. Prevalence and course of sleep problems in childhood. *Sleep.* 2007 Oct;30(10):1371-7. doi: 10.1093/sleep/30.10.1371. PMID: 17969471; PMCID: PMC2266270.

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 "2024 Financial Guidance" above, and statements regarding Vanda's plans to strengthen and grow its business and diversify its sources of revenue; Vanda's plans for pursuit of FDA approval of milsaperidone for the treatments of schizophrenia and acute bipolar I disorder, tradipitant for the treatments of motion sickness and gastroparesis, and HETLIOZ[®] for the treatments of jet lag disorder and insomnia; European Medicines Agency action on the Marketing Authorization Application for HETLIOZ[®] and HETLIOZ LQ[®] for Smith-Magenis Syndrome; Vanda's clinical development plans for milsaperidone for the treatment of MDD, the LAI formulation of Fanapt[®], PONVORY[®] for the treatments of psoriasis and ulcerative colitis, tradipitant for the prevention of vomiting induced by a GLP-1 analog, VSJ-110 for the treatment of dry eye, VPO-227 for the treatment of cholera, VCA-894A for the treatment of CMT2S, VTR-297 for the treatment of onychomycosis and VQW-765 for the treatment of acute performance anxiety in social situations; the initial market response to the commercial launch of Fanapt[®] for the acute treatment of bipolar I in adults; the prevalence of pediatric sleep disorders; the regulatory status of Vanda's Marketing Authorization Application for HETLIOZ[®] and HETLIOZ LQ[®] for SMS in Europe and its NDA for tradipitant for the treatment of symptoms of gastroparesis in the U.S.; and Vanda's plans to continue to support the tradipitant expanded access program for gastroparesis patients 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 correct the deficiencies identified by the FDA in the CRL with respect to the NDA for tradipitant for the treatment of symptoms of gastroparesis; Vanda's ability to complete and submit to the FDA the NDAs for tradipitant for the treatment of motion sickness and milsaperidone for the treatments of schizophrenia and acute bipolar I disorder within the specified timeframes; the FDA's assessment of the sufficiency of the data packages to be included in the NDAs for tradipitant and milsaperidone; Vanda's ability to correct the deficiencies identified by the FDA in the Complete Response Letter (CRL) with respect to the sNDA for HETLIOZ[®] for the treatment of insomnia; the outcome in the U.S. Court of Appeals of Vanda's challenge to the FDA's rejection of its sNDA for HETLIOZ[®] for the treatment of jet lag disorder; the accuracy of the lead indicators regarding the initial market response to the commercial launch of Fanapt[®] for the acute treatment of bipolar I disorder in adults; Vanda's ability to initiate the Phase III programs for milsaperidone for MDD and the LAI formulation of Fanapt[®] by the end of 2024; the accuracy of the estimates regarding the prevalence of pediatric sleep disorders; Vanda's ability to file the INDs for PONVORY[®] for the treatments of psoriasis and ulcerative colitis by the end of 2024; Vanda's ability to initiate the Phase I study for VPO-227 for the treatment of cholera by the end of 2024; Vanda's ability to enroll the patient for the Phase I study for VCA-894A for the treatment of CMT2S by the end of 2024; and Vanda's ability to complete the Phase I study of VTR-297 for the treatment of onychomycosis by the end of 2024. 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.

	Three Months Ended		Nine Months Ended	
	September 30 2024	September 30 2023	September 30 2024	September 30 2023
Revenues:				
Fanapt® net product sales	\$ 23,919	\$ 21,315	\$ 67,648	\$ 68,274
HETLIOZ® net product sales	17,870	17,500	56,631	79,095
PONVORY® net product sales	5,862	—	21,308	—
Total revenues	47,651	38,815	145,587	147,369
Operating expenses:				
Cost of goods sold excluding amortization	2,551	3,063	8,724	11,336
Research and development	16,776	16,600	54,591	52,484
Selling, general and administrative	37,573	24,767	107,132	89,270
Intangible asset amortization	1,751	380	5,521	1,137
Total operating expenses	58,651	44,810	175,968	154,227
Loss from operations	(11,000)	(5,995)	(30,381)	(6,858)
Other income	4,756	5,875	13,957	14,858
Income (loss) before income taxes	(6,244)	(120)	(16,424)	8,000
Provision (benefit) for income taxes	(920)	(257)	(2,436)	3,091
Net income (loss)	\$ (5,324)	\$ 137	\$ (13,988)	\$ 4,909
Net income (loss) per share, basic	\$ (0.09)	\$ 0.00	\$ (0.24)	\$ 0.09
Net income (loss) per share, diluted	\$ (0.09)	\$ 0.00	\$ (0.24)	\$ 0.09
Weighted average shares outstanding, basic	58,261,961	57,519,031	58,095,566	57,329,969
Weighted average shares outstanding, diluted	58,261,961	57,595,344	58,095,566	57,512,225

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

	September 30 2024	December 31 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 100,497	\$ 135,821
Marketable securities	275,764	252,443
Accounts receivable, net	42,753	34,155
Inventory	1,614	1,357
Prepaid expenses and other current assets	11,759	9,170
Total current assets	432,387	432,946
Property and equipment, net	2,178	2,037
Operating lease right-of-use assets	6,016	7,103
Intangible assets, net	115,848	121,369
Deferred tax assets	79,363	75,000
Non-current inventory and other	9,323	9,985
Total assets	\$ 645,115	\$ 648,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 39,304	\$ 38,460
Product revenue allowances	49,786	49,237
Total current liabilities	89,090	87,697
Operating lease non-current liabilities	5,486	7,006
Other non-current liabilities	9,316	8,827
Total liabilities	103,892	103,530
Stockholders' equity:		
Common stock	58	58
Additional paid-in capital	709,843	700,274
Accumulated other comprehensive income (loss)	702	(30)
Accumulated deficit	(169,380)	(155,392)
Total stockholders' equity	541,223	544,910

Total liabilities and stockholders' equity	\$	645,115	\$	648,440
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