Vanda Pharmaceuticals Reports Second Quarter 2024 Financial Results

July 31, 2024

- *Revenues for Q2 2024 were $50.5 million, an increase of 6% compared to Q1 2024 and an increase of 10% compared to Q2 2023*
- *Financial Guidance reinstated for Full Year 2024*
- *Fanapt® approved for the acute treatment of bipolar I disorder; commercial launch initiated in Q3 2024*
- *PONVORY® commercial launch in multiple sclerosis initiated in Q3 2024*
- *Tradipitant NDA review for gastroparesis ongoing; PDUFA date of September 18, 2024*
- *Positive results for tradipitant second Phase III motion sickness study results announced in May 2024; NDA expected to be submitted in Q4 2024*

WASHINGTON, July 31, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2024.

"2024 has been marked by the achievement of significant clinical development milestones and the expansion of our commercial organization to support the commercialization of Fanapt in bipolar disorder and Ponvory in multiple sclerosis," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board. "The expansion of our commercial operations positions us well for future growth as we advance our clinical development pipeline with late-stage and early-stage assets."

Financial Highlights

Second Quarter of 2024

- Total net product sales from Fanapt®, HETLIOZ® and PONVORY® were $50.5 million in the second quarter of 2024, a 10% increase compared to $46.1 million in the second quarter of 2023, and a 6% increase compared to $47.5 million in the first quarter of 2024.
- Fanapt® net product sales were $23.2 million in the second quarter of 2024, a 4% decrease compared to $24.1 million in the second quarter of 2023, and a 12% increase compared to $20.6 million in the first quarter of 2024.
- HETLIOZ® net product sales were $18.7 million in the second quarter of 2024, a 15% decrease compared to $22.0 million in the second quarter of 2023, and a 7% decrease compared to $20.1 million in the first quarter of 2024. The decrease relative to the second quarter of 2023 was the result of continued generic competition in the U.S.
- PONVORY® net product sales were $8.6 million in the second quarter of 2024, an increase of 26% compared to $6.8 million in the first 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 $4.5 million in the second quarter of 2024, compared to net income of $1.5 million in the second quarter of 2023, and net loss of $4.1 million in the first quarter of 2024.
- Cash, cash equivalents and marketable securities (Cash) was $387.7 million as of June 30, 2024, representing a decrease to Cash of $6.5 million compared to March 31, 2024.

First Six Months of 2024

- Total net product sales from Fanapt®, HETLIOZ® and PONVORY® were $97.9 million in the first six months of 2024, a 10% decrease compared to $108.6 million in the first six months of 2023.
- Fanapt® net product sales were $43.7 million in the first six months of 2024, a 7% decrease compared to $47.0 million in the first six months of 2023.
- HETLIOZ® net product sales were $38.8 million in the first six months of 2024, a 37% decrease compared to $61.6 million in the first six months of 2023. The decrease relative to the first six months of 2023 was the result of continued generic competition in the U.S.
- PONVORY® net product sales were $15.4 million in the first six months of 2024. The acquisition of PONVORY® from Janssen was completed on December 7, 2023.
- Net loss was $8.7 million in the first six months of 2024, compared to net income of $4.8 million in the first six months of 2023.
- Cash was $387.7 million as of June 30, 2024, representing a decrease to Cash of $0.6 million compared to December 31, 2023.

Key Operational Highlights

Psychiatry Portfolio

- Fanapt® (iloperidone): Vanda initiated the commercial launch of Fanapt® for the treatment of bipolar I disorder in adults in the third quarter of 2024, including the expansion of its existing sales force and the introduction of prescriber awareness and comprehensive marketing programs.
- 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 treatment of schizophrenia and acute bipolar I disorder to the U.S. Food and Drug Administration (FDA) in early 2025.
- Iloperidone LAI: Vanda expects to initiate a Phase III program for the long acting injectable (LAI) formulation of Fanapt® by the end 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.[1,2] There are currently no approved treatments for pediatric insomnia.
- Vanda continues to pursue FDA approval for HETLIOZ® for the treatment 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 lawsuit asserting that U.S. Patent No. 11,285,129 will be infringed by generic versions of HETLIOZ® marketed by Teva Pharmaceuticals USA, Inc. (Teva) and Apotex Inc. and Apotex Corp. (Apotex) is currently pending in the U.S. District Court for the District of Delaware. Vanda announced in July 2024 that the District Court ordered that Vanda's HETLIOZ® lawsuit may proceed.
- Vanda submitted a Marketing Authorization Application for HETLIOZ® and a Line Extension Application for HETLIOZ LQ® to the European Medicines Agency for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome.

PONVORY® (ponesimod)

- Vanda announced in May 2024 that ownership of the U.S. NDA and Investigational New Drug (IND) applications for PONVORY® had been transferred to Vanda from a Johnson & Johnson Company. Vanda initiated the commercial launch of PONVORY® for the treatment of relapsing forms of multiple sclerosis in the third quarter of 2024 including the deployment of a specialty sales force.
- Vanda expects to file IND applications with the FDA for PONVORY® in the treatment of psoriasis and ulcerative colitis, in 2024.

Tradipitant

- The NDA for tradipitant for the treatment of symptoms of gastroparesis is under review by the FDA with a PDUFA target action date of September 18, 2024. Although the review is ongoing, the FDA provided a preliminary notice that deficiencies preclude discussion of labeling. Gastroparesis is a significant unmet medical need with the last treatment option approved over 40 years ago and an estimated prevalence in the U.S. of over 6 million individuals.[3]
- In May 2024, Vanda announced positive results from the second Phase III study of tradipitant for the treatment of motion sickness. Vanda expects to submit an NDA for the treatment of motion sickness to the FDA in the fourth quarter of 2024. An eventual NDA approval of tradipitant for the treatment of motion sickness would significantly expand the addressable patient population, with approximately 30% of the U.S. population reported to suffer from motion sickness under ordinary travel conditions that include travel by sea, air and land.[4]

Early-Stage Programs

- 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 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 in mid-2024.
- The Phase I clinical study of VTR-297 for the treatment of onychomycosis, a fungal infection of the nail, was initiated in April 2024. The study is over 75% enrolled and is expected to be completed in the third quarter 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 $4.5 million in the second quarter of 2024 compared to net income of $1.5 million in the second quarter of 2023. Diluted net loss per share was $0.08 in the second quarter of 2024 compared to diluted net income per share of $0.03 in the second quarter of 2023.

Net loss was $8.7 million in the first six months of 2024 compared to net income of $4.8 million in the first six months of 2023. Diluted net loss per share was $0.15 in the first six months of 2024 compared to diluted net income per share of $0.08 in the first six months of 2023.

2024 Financial Guidance

Vanda reinstates financial guidance and expects to achieve the following financial objectives in 2024:

Full Year 2024 Financial Objectives	Full Year 2024 Guidance
Total revenues	$180 to $210 million
Year-end 2024 Cash	$360 to $390 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, July 31, 2024, at 4:30 PM ET. During the call, Vanda's management will discuss the second 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 1278669. A replay of the call will be available on Wednesday, July 31, 2024, beginning at 8:30 PM ET and will be accessible until Wednesday, August 7, 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 1278669.

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. 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.
2. Fricke-Oerkermann L, Plück J, Schredl M, Heinz K, Mitschke A, Wiater A, Lehmkuhl 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.
3. Rey et al J Neurogastroenterol Motil, Jan 2012.
4. Turner M, Griffin MJ. Motion sickness in public road transport: passenger behavior and susceptibility. Ergonomics. 1999: 42: 444-461.

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 for pursuit of FDA approval of tradipitant for the treatment of motion sickness, milsaperidone for the treatments of schizophrenia and acute bipolar I disorder, and HETLIOZ® for the treatments of insomnia and jet lag disorder; Vanda's clinical development plans for the LAI formulation of Fanapt®, PONVORY® for the treatments of psoriasis and ulcerative colitis, VPO-227 for the treatment of cholera, VCA-894A for the treatment of CMT2S, and VTR-297 for the treatment of onychomycosis; the prevalence of pediatric sleep disorders; the regulatory status of the Company's NDA for tradipitant for the treatment of symptoms of gastroparesis; the prevalence of gastroparesis; the commercial opportunity for tradipitant for the treatment of motion sickness; and the impact of generic competition on sales of HETLIOZ® in future periods 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 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 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; Vanda's ability to initiate the Phase III program for 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, and initiate the Phase III studies for, PONVORY® for the treatments of psoriasis and ulcerative colitis by the end of 2024; the outcome of the FDA's review of Vanda's NDA for tradipitant for the treatment of symptoms of gastroparesis; the accuracy of the estimates regarding the prevalence of gastroparesis; Vanda's ability to enroll patients and 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 mid-2024; Vanda's ability to continue to enroll patients and complete the Phase I study of VTR-297 for the treatment of onychomycosis in the third quarter of 2024; and the ability of generic competitors to increase their share of the market for HETLIOZ®. 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 2024	June 30 2023	June 30 2024	June 30 2023
Revenues:				
Fanapt® net product sales	$ 23,150	$ 24,077	$ 43,729	$ 46,959
HETLIOZ® net product sales	18,708	21,979	38,761	61,595
PONVORY® net product sales	8,616	—	15,446	—
Total revenues	50,474	46,056	97,936	108,554
Operating expenses:				
Cost of goods sold excluding amortization	2,733	3,499	6,173	8,273
Research and development	16,661	16,647	37,815	35,884
Selling, general and administrative	39,474	28,399	69,559	64,503
Intangible asset amortization	1,752	378	3,770	757
Total operating expenses	60,620	48,923	117,317	109,417

Loss from operations	(10,146)	(2,867)	(19,381)	(863)
Other income	4,630	5,459	9,201	8,983
Income (loss) before income taxes	(5,516)	2,592	(10,180)	8,120
Provision (benefit) for income taxes	(998)	1,072	(1,516)	3,348
Net income (loss)	$ (4,518)	$ 1,520	$ (8,664)	$ 4,772
Net income (loss) per share, basic	$ (0.08)	$ 0.03	$ (0.15)	$ 0.08
Net income (loss) per share, diluted	$ (0.08)	$ 0.03	$ (0.15)	$ 0.08
Weighted average shares outstanding, basic	58,220,838	57,453,916	57,990,890	57,233,878
Weighted average shares outstanding, diluted	58,220,838	57,535,615	57,990,890	57,469,105

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

	June 30 2024	December 31 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,953	$ 135,821
Marketable securities	284,723	252,443
Accounts receivable, net	41,864	34,155
Inventory	1,469	1,357
Prepaid expenses and other current assets	8,171	9,170
Total current assets	439,180	432,946
Property and equipment, net	2,303	2,037
Operating lease right-of-use assets	6,375	7,103
Intangible assets, net	117,599	121,369
Deferred tax assets	76,559	75,000
Non-current inventory and other	9,355	9,985
Total assets	$ 651,371	$ 648,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 39,598	$ 38,460
Product revenue allowances	54,193	49,237
Total current liabilities	93,791	87,697
Operating lease non-current liabilities	6,005	7,006
Other non-current liabilities	9,059	8,827
Total liabilities	108,855	103,530
Stockholders' equity:		
Common stock	58	58
Additional paid-in capital	706,844	700,274
Accumulated other comprehensive loss	(330)	(30)
Accumulated deficit	(164,056)	(155,392)
Total stockholders' equity	542,516	544,910
Total liabilities and stockholders' equity	$ 651,371	$ 648,440

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