



Lantheus Reports Third Quarter 2024 Financial Results

Nov 6, 2024

- Worldwide revenue of \$378.7 million, an increase of 18.4% from third quarter 2023
- GAAP fully diluted earnings per share of \$1.79, compared to \$1.88 in the third quarter of 2023. Adjusted fully diluted earnings per share of \$1.70 compared to \$1.47 in the third quarter of 2023
- Company narrows full year 2024 revenue and fully diluted earnings per share guidance towards higher end of the previously issued guidance
- Company applauds CMS' CY25 rule to improve payment for specialized diagnostic radiopharmaceuticals, including PYLARIFY, advancing patient access and care
- Company announced that it expanded its Alzheimer's disease radiodiagnostics portfolio with NAV-4694, a novel, next generation late-stage beta-amyloid imaging agent

BEDFORD, Mass., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (Lantheus or the Company) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today reported financial results for its third quarter ended September 30, 2024.

"PYLARIFY is on track to exceed \$1 billion in sales in 2024 and maintain its market leadership and blockbuster status in 2025," said Brian Markison, Chief Executive Officer of Lantheus. "The success of our flagship diagnostic agents enables us to invest, organically and inorganically in our pipeline to advance our radiopharmaceutical leadership. We are excited about our growing portfolio, especially oncology radiotherapeutics and Alzheimer's disease radiodiagnostics, and will continue to expand our portfolio of late-stage and high potential early-stage product candidates. We are driving growth and shareholder value through operational excellence, financial discipline and prudent capital deployment."

Summary Financial Results

<i>(in millions, except per share data – unaudited)</i>	Three Months Ended September 30,		
	2024	2023	% Change
Worldwide revenue	\$ 378.7	\$ 319.9	18.4%
GAAP net income	\$ 131.1	\$ 132.0	(0.7)%
GAAP fully diluted earnings per share	\$ 1.79	\$ 1.88	(4.8)%
Adj. net income (non-GAAP)	\$ 124.1	\$ 103.1	20.4%
Adj. fully diluted earnings per share (non-GAAP)	\$ 1.70	\$ 1.47	15.6%

Third Quarter 2024

- Worldwide revenue increased 18.4% to \$378.7 million compared to the same period in 2023.
- Sales of PYLARIFY were \$259.8 million, an increase of 20.6%. Growth was driven by increasing volumes at existing accounts with a slight net price offset as we secured strategic partnerships.
- Sales of DEFINITY were \$77.0 million, an increase of 14.3%. Growth was driven by market growth and opportunistic sales due to competitor supply challenges.
- Operating income increased 19.0% to \$133.7 million. Adjusted operating income (non-GAAP) increased 18.3% to \$165.1 million.
- Fully diluted earnings per share decreased to \$1.79, compared to \$1.88 in the prior year period. Adjusted fully diluted earnings per share (non-GAAP) increased 15.6% to \$1.70, compared to \$1.47 in the prior year period.
- Net cash provided by operating activities and free cash flow were \$175.1 million and \$159.3 million, respectively.

Balance Sheet

- At September 30, 2024, the Company's cash and cash equivalents grew to \$866.4 million, compared to \$713.7 million at December 31, 2023, even after accounting for the \$35.0 million net investment related to the acquisition of RM2 from Life Molecular, a \$5 million equity investment in Radiopharm Theranostics as well as a \$10 million milestone payment related to the NAV-4694 asset in the third quarter 2024.
- The Company currently has access to up to \$350.0 million from a revolving line of credit.

Recent Business Highlights

Radiopharmaceutical Pipeline Progress

- The Company announced an expansion of its Alzheimer's disease portfolio in the third quarter, acquiring NAV-4694, a novel, next generation beta-amyloid imaging agent in Phase 3 clinical development. NAV-4694 complements MK-6240, Lantheus' novel, next-generation, tau radiodiagnostic. The Company plans to submit New Drug Applications for MK-6240 in 2025 and NAV-4694 in 2026.
- With respect to the SPLASH Phase 3 registrational study of PNT2002, the second interim analysis performed at 75% of protocol specified events demonstrated results for radiographic progression free survival (rPFS) and overall survival (OS) that did not materially change from the initial interim analysis conducted at 46% of specified events. PNT2002 is an investigational PSMA-targeted radiotherapeutic for the treatment of patients with metastatic castration-resistant prostate cancer. The SPLASH study met its primary endpoint of rPFS, which was a meaningful and statistically significant improvement for the PNT2002 arm vs. the alternate androgen receptor pathway inhibitor (ARPI) or hormone therapy. The OS results and hazard ratio in the intention-to-treat (ITT) population remain confounded by the overwhelming number of patients who crossed over to receive PNT2002. Crossover adjusted analyses are post-hoc, and the Company will continue to review the data and perform additional sub-set analyses with our partner, Eli Lilly, that may be compelling to the FDA in preparation for an interaction on our path forward.

Other Key Updates

- The Centers for Medicare & Medicaid Services (CMS) released its final Medicare Hospital Outpatient Prospective Payment System (OPPS) rule for calendar year 2025 which included improved payment for specialized diagnostic radiopharmaceuticals to support patient access for Medicare fee-for-service (FFS) beneficiaries. In the rule, innovative diagnostic radiopharmaceuticals, including PYLARIFY, will be paid separately by CMS for traditional Medicare FFS patients in the hospital outpatient setting following the expiry of transitional pass-through payment status. The final rule will take effect January 1, 2025.

Full Year 2024 Financial Guidance

	Guidance Issued November 6, 2024	Guidance Issued July 31, 2024
FY 2024 Revenue	\$1.51 billion - \$1.52 billion	\$1.50 billion - \$1.52 billion
FY 2024 Adjusted Fully Diluted EPS	\$6.65 - \$6.70	\$6.60 - \$6.70

On a forward-looking basis, the Company does not provide GAAP income per common share guidance or a reconciliation of GAAP income per common share to adjusted fully diluted EPS because the Company is unable to predict with reasonable certainty business development and acquisition related expenses, purchase accounting fair value adjustments, and any one-time, non-recurring charges. These items are uncertain, depend on various factors, and could be material to results computed in accordance with GAAP. As a result, it is the Company's view that a quantitative reconciliation of adjusted fully diluted EPS on a forward-looking basis is not available without unreasonable effort.

Conference Call and Webcast

As previously announced, the Company will host a conference call and webcast on Wednesday, November 6, 2024, at 8:00 a.m. ET. To access the conference call or webcast, participants should register online at <https://investor.lantheus.com/news-events/calendar-of-events>.

A replay will be available approximately two hours after completion of the webcast and will be archived on the same web page for at least 30 days.

The conference call will include a discussion of non-GAAP financial measures. Reference is made to the most directly comparable GAAP financial measures, the reconciliation of the differences between the two financial measures, and the other information included in this press release, our Form 8-K filed with the SEC today, or otherwise available in the Investor Relations section of our website located at www.lantheus.com.

The conference call may include forward-looking statements. See the cautionary information about forward-looking statements in the safe-harbor section of this press release.

About Lantheus Holdings, Inc.

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in Canada and Sweden, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. For more information, visit www.lantheus.com.

Internet Posting of Information

The Company routinely posts information that may be important to investors in the "Investors" section of its website at www.lantheus.com. The Company encourages investors and potential investors to consult its website regularly for important information about the Company.

Non-GAAP Financial Measures

The Company uses non-GAAP financial measures, such as adjusted net income and its line components; adjusted net income per share - fully diluted; adjusted operating income and free cash flow. The Company's management believes that the presentation of these measures provides useful information to investors. These measures may assist investors in evaluating the Company's operations, period over period. However, these measures may exclude items that may be highly variable, difficult to predict and of a size that could have a substantial impact on the Company's reported results of operations for a particular period. Management uses these and other non-GAAP measures internally for evaluation of the performance of the business, including the allocation of resources and the evaluation of results relative to employee performance compensation targets. Investors should consider these non-GAAP measures only as a supplement to, not as a substitute for or as superior to, measures of financial performance prepared in accordance with GAAP.

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as "advance," "believe," "continue," "could," "driving," "guidance," "maintain," "may," "on track," "plan," "potential," "predict," "progress," "should," "target," "will," "would" and other similar terms. Such forward-looking statements include our guidance for the fiscal year 2024 and our plans to expand our portfolio of late-stage assets and high potential early-stage candidates and are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include: (i) continued market expansion and penetration for our established commercial products, particularly PYLARIFY and DEFINITY, in a competitive environment in which other imaging agents have been approved and are being commercialized, and our ability to clinically and commercially differentiate our products; (ii) our ability to have third parties manufacture our products and our ability to manufacture DEFINITY in our in-house manufacturing facility; (iii) the global availability of Molybdenum-99 ("Mo-99") and other raw material and key components; (iv) our strategies, future prospects, and our projected growth, including revenue related to our collaboration agreements with POINT Biopharma Global Inc., including our ability to obtain FDA approval for PNT2002 and PNT2003; (v) our ability to satisfy our obligations under our existing clinical development partnerships using MK-6240 or NAV-4694 as a research tool and under the license agreements through which we have rights to MK-6240 and NAV-4694, and to further develop and commercialize MK-6240 and NAV-4694 as approved products; (vi) our ability to successfully execute on our agreements with Perspective Therapeutics, Inc. ("Perspective"), including finalizing the license agreements in the event we exercise our options to do so, the value of our current and any future equity interest in Perspective, and Perspective's ability to successfully develop its alpha-particle therapy and innovative platform technology; (vii) our ability to successfully identify strategic transaction opportunities, such as our investment in Radiopharm Theranostics Limited ("Radiopharm") common stock, and the value of such current and any future equity interests; (viii) the efforts and timing for clinical development, regulatory approval, adequate coding, coverage and payment and successful commercialization of our product candidates and new clinical applications and territories for our products, in each case, that we or our strategic partners may undertake; (ix) our ability to identify and acquire or in-license additional diagnostic and therapeutic product opportunities in oncology, Alzheimer's disease and other strategic areas and continue to grow and advance our pipeline of products; and (x) the risk and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

- Tables Follow -

Lantheus Holdings, Inc.

Consolidated Statements of Operations

(in thousands, except per share data – unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	\$	\$	\$	\$
Revenues	\$ 378,734	\$ 319,946	\$ 1,142,800	\$ 942,430
Cost of goods sold	136,608	119,995	403,054	462,756
Gross profit	<u>242,126</u>	<u>199,951</u>	<u>739,746</u>	<u>479,674</u>
Operating expenses				
Sales and marketing	43,719	37,399	134,300	106,472
General and administrative	40,516	35,741	135,820	85,163
Research and development	24,148	14,450	132,773	60,883
Total operating expenses	<u>108,383</u>	<u>87,590</u>	<u>402,893</u>	<u>252,518</u>
Gain on sale of assets	—	—	6,254	—
Operating income	133,743	112,361	343,107	227,156
Interest expense	4,903	5,054	14,624	14,978
Investment in equity securities - unrealized gain	(37,325)	—	(75,492)	—
Other income	(9,953)	(52,649)	(27,785)	(60,362)
Income before income taxes	176,118	159,956	431,760	272,540
Income tax expense	45,025	27,999	107,528	49,259
Net income	<u>\$ 131,093</u>	<u>\$ 131,957</u>	<u>\$ 324,232</u>	<u>\$ 223,281</u>
Net income per common share:				
Basic	\$ 1.89	\$ 1.93	\$ 4.69	\$ 3.27
Diluted	<u>\$ 1.79</u>	<u>\$ 1.88</u>	<u>\$ 4.55</u>	<u>\$ 3.18</u>
Weighted-average common shares outstanding:				
Basic	69,464	68,436	69,193	68,188
Diluted	<u>73,065</u>	<u>70,046</u>	<u>71,331</u>	<u>70,268</u>

Lantheus Holdings, Inc.

Consolidated Revenues Analysis

(in thousands – unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	% Change	2024	2023	% Change
	\$	\$		\$	\$	
PYLARIFY	\$ 259,756	\$ 215,428	20.6%	\$ 791,881	\$ 621,419	27.4%
Other radiopharmaceutical oncology	—	848	(100.0)%	384	2,383	(83.9)%
Total radiopharmaceutical oncology	<u>259,756</u>	<u>216,276</u>	<u>20.1%</u>	<u>792,265</u>	<u>623,802</u>	<u>27.0%</u>
DEFINITY	76,965	67,336	14.3%	231,629	206,688	12.1%
TechneLite	20,480	23,272	(12.0)%	70,380	65,853	6.9%
Other precision diagnostics	6,282	5,740	9.4%	18,039	17,002	6.1%
Total precision diagnostics	<u>103,727</u>	<u>96,348</u>	<u>7.7%</u>	<u>320,048</u>	<u>289,543</u>	<u>10.5%</u>
Strategic partnerships and other revenue	15,251	7,322	108.3%	30,487	29,085	4.8%
Total revenues	<u>\$ 378,734</u>	<u>\$ 319,946</u>	<u>18.4%</u>	<u>\$ 1,142,800</u>	<u>\$ 942,430</u>	<u>21.3%</u>

Lantheus Holdings, Inc.

Reconciliation of GAAP to Non-GAAP Financial Measures

(in thousands, except per share data – unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	\$ 131,093	\$ 131,957	\$ 324,232	\$ 223,281
Net income				
Stock and incentive plan compensation	20,366	13,976	54,229	36,335
Amortization of acquired intangible assets	11,908	11,659	31,961	35,132
Campus consolidation costs	23	45	37	3,185
Contingent consideration fair value adjustments	(1,505)	(500)	(1,405)	(9,475)
Non-recurring refinancing related fees	—	3	—	216
Non-recurring fees	—	(51,789)	—	(54,523)
Gain on sale of assets	—	—	(6,254)	—
Strategic collaboration and license costs	30	—	66,221	—
Investment in equity securities - unrealized gain	(37,325)	—	(75,492)	—
Acquisition-related costs	(263)	169	1,346	507
Impairment of long-lived assets	—	—	—	138,050
ARO Acceleration and other related costs	—	320	—	1,045
Other	805	1,510	2,273	2,194
Income tax effect of non-GAAP adjustments ^(a)	(1,048)	(4,256)	(27,907)	(61,093)
Adjusted net income	\$ 124,084	\$ 103,094	\$ 369,241	\$ 314,854
Adjusted net income, as a percentage of revenues	32.8%	32.2%	32.3%	33.4%

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	\$ 1.79	\$ 1.88	\$ 4.55	\$ 3.18
Net income per share - diluted				
Stock and incentive plan compensation	0.28	0.20	0.76	0.52
Amortization of acquired intangible assets	0.16	0.17	0.45	0.50
Campus consolidation costs	—	—	—	0.05
Contingent consideration fair value adjustments	(0.02)	(0.01)	(0.02)	(0.13)
Non-recurring refinancing related fees	—	—	—	—
Non-recurring fees	—	(0.74)	—	(0.78)
Gain on sale of assets	—	—	(0.09)	—
Strategic collaboration and license costs	—	—	0.93	—
Investment in equity securities - unrealized gain	(0.51)	—	(1.06)	—
Acquisition-related costs	—	—	0.02	0.01
Impairment of long-lived assets	—	—	—	1.96
ARO Acceleration and other related costs	—	0.01	—	0.01
Other	0.01	0.02	0.03	0.03
Income tax effect of non-GAAP adjustments ^(a)	(0.01)	(0.06)	(0.39)	(0.87)
Adjusted net income per share - diluted	\$ 1.70	\$ 1.47	\$ 5.18	\$ 4.48
Weighted-average common shares outstanding - diluted	73,065	70,046	71,331	70,268

(a) The income tax effect of the adjustments between GAAP net income and adjusted net income (non-GAAP) takes into account the tax treatment and related tax rate that apply to each adjustment in the applicable tax jurisdiction.

Lantheus Holdings, Inc.

Reconciliation of GAAP to Non-GAAP Financial Measures (Continued)

(in thousands, except per share data – unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2024		2023					
	\$	133,743	\$	112,361	\$	343,107	\$	227,156
Operating income								
Stock and incentive plan compensation		20,366		13,976		54,229		36,335
Amortization of acquired intangible assets		11,908		11,659		31,961		35,132
Campus consolidation costs		23		45		37		3,185
Contingent consideration fair value adjustments		(1,505)		(500)		(1,405)		(9,475)
Non-recurring refinancing related fees		—		3		—		216
Non-recurring fees		—		—		—		(2,734)
Gain on sale of assets		—		—		(6,254)		—
Strategic collaboration and license costs		30		—		66,221		—
Acquisition-related costs		(263)		169		1,346		507
Impairment of long-lived assets		—		—		—		138,050
ARO Acceleration and other related costs		—		320		—		1,045
Other		805		1,510		2,273		2,194
Adjusted operating income	\$	165,107	\$	139,543	\$	491,515	\$	431,611
Adjusted operating income, as a percentage of revenues		43.6%		43.6%		43.0%		45.8%

Lantheus Holdings, Inc.

Reconciliation of Free Cash Flow

(in thousands – unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2024		2023					
	\$	175,062	\$	116,739	\$	387,020	\$	192,973
Net cash provided by operating activities	\$	(15,808)	\$	(14,621)	\$	(35,256)	\$	(34,486)
Capital expenditures	\$	159,254	\$	102,118	\$	351,764	\$	158,487
Free cash flow	\$	(67,798)	\$	83,218	\$	(219,413)	\$	18,008
Net cash (used in) provided by investing activities	\$	1,869	\$	108	\$	(14,877)	\$	(12,612)
Net cash provided by (used in) financing activities	\$		\$		\$		\$	

Lantheus Holdings, Inc.

Condensed Consolidated Balance Sheets

(in thousands – unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 866,386	\$ 713,656
Accounts receivable, net	329,336	284,292
Inventory	70,835	64,029
Other current assets	21,998	16,683
Assets held for sale	7,159	7,159
Total current assets	1,295,714	1,085,819

Investment in equity securities	158,791	—
Property, plant and equipment, net	169,512	146,697
Intangibles, net	173,606	151,985
Goodwill	61,189	61,189
Deferred tax assets, net	144,641	150,198
Other long-term assets	46,177	55,261
Total assets	\$ 2,049,630	\$ 1,651,149
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	\$ 564,713	\$ 823
Accounts payable	44,914	41,189
Accrued expenses and other liabilities	174,452	145,338
Total current liabilities	784,079	187,350
Asset retirement obligations	23,237	22,916
Long-term debt, net and other borrowings	613	561,670
Other long-term liabilities	61,993	63,321
Total liabilities	869,922	835,257
Commitments and contingencies (See Note 18)		
Stockholders' equity		
Preferred stock (\$0.01 par value, 25,000 shares authorized; no shares issued and outstanding)	—	—
Common stock (\$0.01 par value, 250,000 shares authorized; 70,854 and 69,863 shares issued as of September 30, 2024 and December 31, 2023, respectively)	709	699
Additional paid-in capital	797,430	757,727
Treasury Stock at cost - 1,339 shares as of September 30, 2024 and December 31, 2023	(75,000)	(75,000)
Retained earnings	457,735	133,503
Accumulated other comprehensive loss	(1,166)	(1,037)
Total stockholders' equity	1,179,708	815,892
Total liabilities and stockholders' equity	\$ 2,049,630	\$ 1,651,149

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