# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

# FORM 8-K

# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 06, 2025

# LANTHEUS HOLDINGS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-36569 (Commission File Number) 35-2318913 (IRS Employer Identification No.)

201 Burlington Road South Building Bedford, Massachusetts (Address of Principal Executive Offices)

01730 (Zip Code)

Registrant's Telephone Number, Including Area Code: (978) 671-8001

Not Applicable (Former Name or Former Address, if Changed Since Last Report)

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	eck the appropriate box below if the Form 8-K filing is is owing provisions:	ntended to simultaneously sa	atisfy the filing obligation of the registrant under any of the
	Written communications pursuant to Rule 425 under the	he Securities Act (17 CFR 2	30.425)
	Soliciting material pursuant to Rule 14a-12 under the	Exchange Act (17 CFR 240.	14a-12)
	Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchang	ge Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchang	ge Act (17 CFR 240.13e-4(c))
	Securities r	registered pursuant to Secti	ion 12(b) of the Act:
		Trading	
	Title of each class	Symbol(s)	Name of each exchange on which registered
	Common stock, par value \$0.01 per share	LNTH	The Nasdaq Global Market
	icate by check mark whether the registrant is an emerging pter) or Rule 12b-2 of the Securities Exchange Act of 19		ed in Rule 405 of the Securities Act of 1933 (§ 230.405 of this oter).
Em	erging growth company		
	n emerging growth company, indicate by check mark if evised financial accounting standards provided pursuant	•	t to use the extended transition period for complying with any new hange Act. $\square$

#### Item 2.02 Results of Operations and Financial Condition.

On August 6, 2025, Lantheus Holdings, Inc. (the "Company") announced via press release its financial results as of and for the three and six months ended June 30, 2025. A copy of that press release is being furnished as Exhibit 99.1 and is hereby incorporated by reference.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

### Item 7.01 Regulation FD Disclosure.

On August 6, 2025, the Company issued a press release announcing that the United States Food and Drug Administration has accepted a new drug application for a new formulation of its piflufolastat F-18 prostate-specific membrane antigen positron emission tomography imaging agent filed by its affiliate, Aphelion LLC. A copy of the press release is being furnished with this Current Report on Form 8-K as Exhibit 99.2 and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

#### Item 8.01 Other Events.

On August 6, 2025, the Company announced that its board of directors has authorized a program to repurchase up to \$400.0 million of shares of its common stock through December 31, 2027 (the "2025 Program"). The 2025 Program replaces the Company's existing repurchase program, which was announced in November 2024. Repurchases under the 2025 Program may be made from time to time through open market transactions at prevailing market prices, in privately negotiated transactions and/or through other legally permissible means, depending on market conditions and in accordance with applicable rules and regulations. The actual timing, number, and dollar amount of repurchase transactions will be determined by the Company's management at its discretion and will depend on a number of factors including, but not limited to, the market price of the Company's common stock. The Company may also establish 10b5-1 trading plans from time to time that will provide flexibility if and when it buys back its common stock. The announcement of the 2025 Program is included in the press release attached hereto as Exhibit 99.1.

# Safe Harbor for Forward-Looking and Cautionary Statements

This report 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 and Section 21E of the Exchange Act. Forward-looking statements may be identified by their use of terms such as "believe," "continue," "could," "guidance," "may," "plan," "potential," "predict," "progress," "should," "target," "will," "would" and other similar terms. These forward-looking statements include the Company's capital allocation plans and are subject to risks and uncertainties the risk and uncertainties discussed in the Company's filings with the Securities and Exchange Commission (including those described in the Risk Factors section in the Company's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q).

# Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Press release of Lantheus Holdings, Inc. dated August 6, 2025, entitled "Lantheus Reports Second Quarter 2025 Financial
99.2*	Results and Provides Business Update"  Press release of Lantheus Holdings, Inc. dated August 6, 2025, entitled "Lantheus Announces FDA Acceptance of NDA for New Formulation for Market-Leading PSMA PET Imaging Agent"

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	104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
*	amended	1 and 99.2 attached hereto are being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, as or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under ities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# LANTHEUS HOLDINGS, INC.

By: /s/ Daniel M. Niedzwiecki

Name: Daniel M. Niedzwiecki

Title: Chief Administrative Officer and General Counsel

Date: August 6, 2025



# Lantheus Reports Second Quarter 2025 Financial Results and Provides Business Update

- Recorded second quarter 2025 worldwide revenue of \$378.0 million, GAAP fully diluted earnings per share of \$1.12, adjusted fully diluted earnings per share of \$1.57 and free cash flow of \$79.1 million
- Announced FDA acceptance of NDA for new formulation for piflufolastat F 18 PSMA PET imaging agent with a PDUFA date of March 6, 2026
- Closed acquisition of Life Molecular Imaging in July, immediately expanding near- and long-term growth profile and commercial portfolio with Neuraceq® (florbetaben F 18 injection), a globally approved beta-amyloid targeted radiodiagnostic for Alzheimer's disease; FDA label expansion for Neuraceq in June
- Board of Directors authorized a program to repurchase up to \$400 million of Lantheus common stock, replacing the 12-month program announced in November 2024
- Provided updated corporate guidance for full year 2025 revenue and adjusted fully diluted earnings per share, reflecting the Life Molecular Imaging acquisition and current business outlook

BEDFORD, Mass., August 6, 2025 (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 second quarter ended June 30, 2025.

"In the second quarter and the month thereafter, we completed the acquisitions of both Evergreen Theragnostics and Life Molecular Imaging – key steps in executing our strategy to expand capabilities across the radiopharmaceutical value chain, diversify revenue, including with Neuraceq, and drive future growth. At the same time, we navigated increased competition in the PSMA PET landscape, which impacted PYLARIFY performance. We are taking actions to reinforce PYLARIFY's clinical differentiation and support the value of our PSMA PET franchise," said Brian Markison, CEO. "Today, we announced the FDA has accepted our NDA for a new PSMA PET formulation and the Board authorized a new \$400 million stock repurchase program, which reflects our confidence in our long-term strategy to deliver value for our business, patients, and shareholders."

# **Summary Financial Results**

	7	hree	Months End	ed
(in millions, except per share data - unaudited)	 2025		2024	% Change
Worldwide revenue	\$ 378.0	\$	394.1	(4.1%)
GAAP net income	\$ 78.8	\$	62.1	26.9%
GAAP fully diluted earnings per share	\$ 1.12	\$	0.88	27.3%
Adjusted net income (non-GAAP)	\$ 110.6	\$	126.8	(12.8%)
Adjusted fully diluted earnings per share (non-GAAP)	\$ 1.57	\$	1.80	(12.8%)

# Second Quarter 2025

- Sales of PYLARIFY were \$250.6 million, a decrease of 8.3%.
- Sales of DEFINITY were \$83.9 million, an increase of 7.5%.
- Operating income decreased 14.4% to \$88.0 million. Adjusted operating income (non-GAAP) decreased 10.8% to \$152.6 million.
- Fully diluted earnings per share increased 27.3% to \$1.12, compared to \$0.88 in the prior year period. Adjusted fully diluted earnings per share (non-GAAP) decreased 12.8% to \$1.57, compared to \$1.80 in the prior year period.

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Net cash provided by operating activities and free cash flow were \$87.1 million and \$79.1 million, respectively.

#### **Balance Sheet**

- At June 30, 2025, the Company's cash and cash equivalents were \$695.6 million, after payment of \$276.4 million for the Evergreen
  Theragnostics, Inc. ("Evergreen") acquisition, which closed early in the second quarter of 2025, compared to \$912.8 million at December 31,
  2024.
- The Company currently has access to up to \$750.0 million from a revolving line of credit.

# **Recent Business Highlights**

#### **Business Development Updates**

- In July, the Company announced the completion of the acquisition of Life Molecular Imaging, a global radiopharmaceutical company dedicated to developing and offering novel cutting-edge radiopharmaceuticals that improve early detection and characterization of chronic and life-threatening diseases. Through the transaction, Lantheus acquired Neuraceq, a globally approved beta-amyloid targeted radiodiagnostic for Alzheimer's disease, as well as an international commercial footprint and infrastructure.
- In June, the FDA approved an updated label for Neuraceq, expanding the clinical indication to include the use in both diagnostic assessment and identification of appropriate candidates for FDA-approved amyloid-targeting therapies. The expanded label also includes the utilization of quantitative amyloid plaque metrics in conjunction with visual image interpretation and broader use for monitoring of therapy and following progression to Alzheimer's disease.
- In May, the Company announced an agreement to sell its SPECT business to Illuminated Holdings, Inc., the parent company of SHINE
  Technologies, LLC ("SHINE"). The transaction allows Lantheus to focus on growing its commercial portfolio of innovative PET
  radiodiagnostics and microbubbles, while advancing its pipeline of radiopharmaceuticals. The transaction is expected to close by the end of the
  year, subject to customary closing conditions.
- In April, the Company announced the completion of the acquisition of Evergreen, a clinical-stage radiopharmaceutical company based in New Jersey. Through the transaction, Lantheus acquired OCTEVY<sup>TM</sup>, a registrational-stage PET imaging agent targeting neuroendocrine tumors, which complements Lantheus' therapeutic candidate PNT2003, and also acquired a portfolio of clinical and pre-clinical theranostic pairs. The acquisition also advances Lantheus' capabilities with the addition of Evergreen's radioligand therapy manufacturing infrastructure, including a revenue-generating CDMO business.

# Radiopharmaceutical Pipeline Updates

- This morning, the Company announced FDA acceptance of a new drug application ("NDA") for a new formulation of piflufolastat F 18 PSMA PET imaging agent. The new formulation will increase batch size by ~50%, which would allow Lantheus to serve significantly more patients while maintaining the same high standards that have made PYLARIFY the trusted choice for providers.
- In April, the Company announced that MK-6240, its next-generation tau imaging agent, met its primary endpoints in two pivotal clinical studies assessing the investigational asset's sensitivity and specificity. The Company plans to submit an NDA to the FDA in the third quarter of 2025.

# Other Key Updates

#### Full Year 2025 Updated Corporate Financial Guidance

	Guidance Issued August 6, 2025	Guidance Issued May 7, 2025
FY 2025 Revenue	\$1.475 billion - \$1.51 billion	\$1.550 billion - \$1.585 billion
FY 2025 Adjusted fully diluted EPS	\$5.50 - \$5.70	\$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, August 6, 2025, 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

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 New Jersey, Canada, Germany, Sweden and Switzerland, Lantheus has been providing radiopharmaceutical solutions for nearly 70 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 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.

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# 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. These forward-looking statements may be identified by their use of terms such as "advance," "believe," "continue," "could," "driving," "expect," "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 2025 and our plans to expand our portfolio of late-stage assets and high potential early-stage candidates, our acquisitions of Evergreen and Life Molecular and our plans to divest our SPECT business to SHINE, 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 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, in amounts and at the times needed; (iii) the availability of raw materials, key components, and equipment, either used in the production of our products and product candidates, or in the use by healthcare professionals ("HCPs") of our products and product candidates, including, but not limited to positron emission tomography ("PET") scanners for PYLARIFY, MK-6240 and NAV-4694; (iv) 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, including the timing for any potential regulatory submissions for these investigational assets; (v) our ability to successfully integrate acquisitions, including of Life Molecular and Evergreen, including the potential for unforeseen expenses related to integration activities, the accuracy of our financial models, the potential for unforeseen liabilities within those businesses, the ability to integrate disparate information technology systems, retain key talent and create a merged corporate culture that successfully realizes the full potential of the combined organization; (vi) our ability to obtain U.S. Food and Drug Administration ("FDA") approval for our new F 18 PSMA PET product candidate, to complete the technology transfer across our PET manufacturing facilities network for such new product candidate, and to obtain adequate coding, coverage and payment, including transitional passthrough payment status, for such new product candidate; (vii) our ability to complete the sale of our single-photon emission computerized tomography ("SPECT") business to SHINE on the proposed terms or on the anticipated timeline, or at all, including risks and uncertainties related to securing the necessary regulatory approvals and satisfaction of other closing conditions to consummate the transaction, unforeseen expenses related to the divestiture, and failure to realize the expected benefits of the transaction; (viii) our ability to obtain FDA approval for LNTH-2501, our investigational kit for the preparation of Gallium-68 DOTATOC, which may be used in conjunction with a PET scan to stage and localize gastroenteropancreatic neuroendocrine tumors in adults and children, and approval for PNT2003, and to be successful in the patent litigation associated with PNT2003; (ix) the cost, 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; (x) our ability to identify opportunities to collaborate with strategic partners and to acquire or in-license additional diagnostic and therapeutic product opportunities in oncology, neurology and other strategic areas and continue to grow and advance our pipeline of products; and (xi) 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).

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# **Consolidated Statements of Operations**

(in thousands, except per share data – unaudited)

	Three Months Ended June 30,					Six Months Ended June 30,				
		2025	2024	2025			2024			
Revenues	\$	378,045	\$	394,091	\$	750,809	\$	764,066		
Cost of goods sold		137,034		138,317		272,098		266,446		
Gross profit		241,011		255,774		478,711		497,620		
Operating expenses	_									
Sales and marketing		41,041		45,035		83,544		90,581		
General and administrative		66,515		47,409		123,331		95,304		
Research and development		45,489		60,601		81,803		108,625		
Total operating expenses		153,045		153,045		288,678		294,510		
Gain on sale of assets		_		_		_		6,254		
Operating income		87,966		102,729		190,033		209,364		
Interest expense		4,917		4,862		9,721		9,721		
Investment in equity securities - unrealized (gain) loss		(14,573)		22,537		289		(38,167)		
Other income		(6,895)		(9,044)		(21,023)		(17,832)		
Income before income taxes		104,517		84,374		201,046		255,642		
Income tax expense		25,762		22,301		49,346		62,503		
Net income	\$	78,755	\$	62,073	\$	151,700	\$	193,139		
Net income per common share:										
Basic	\$	1.15	\$	0.89	\$	2.21	\$	2.80		
Diluted	\$	1.12	\$	0.88	\$	2.14	\$	2.74		
Weighted average common shares outstanding:										
Basic		68,516		69,356		68,591		69,056		
Diluted		70,312		70,601		70,896		70,364		

# **Consolidated Revenues Analysis**

(in thousands, except percent data – unaudited)

**Three Months Ended** Six Months Ended June 30. June 30 **2025** 250,642 2024 Change % (4.5)% (100.0)% Change \$ (22,613) Change \$ (23,829) (384) Change % 2025 PYLARIFY Other radiopharmaceutical oncology (8.3)% —% (8.3)% 273,255 508,296 532,125 250,642 273,255 (22,613) 508,296 532,509 (24,213) Total radiopharmaceutical oncology (4.5)% 24,215) 8,486 (5,207) 576 3,855 7,101 (13,257) 78,100 28,186 5,825 112,111 8,725 394,091 163,150 44,693 12,333 220,176 22,337 750,809 7.5% (11.4)% 18.3% 3.3% 32.8% 154,664 49,900 11,757 216,321 15,236 DEFINITY TechneLite Other precision diagnostics 5,839 (3,204) 1,067 5.5% (10.4)% 4.9% 83,939 24,982 24,982 6,892 115,813 11,590 378,045 3,702 2,865 Total precision diagnostics 1.8% 46.6 % (1.7)% Strategic partnerships and other revenue Total revenues (16,046) (4.1)% 764,066

# Reconciliation of GAAP to Non-GAAP Financial Measures

(in thousands, except per share and percent data – unaudited)

	Three Months Ended June 30,				Six Months Ended June 30,			
	2025		2024		2025		2024	
Net income	\$ 78,755	<u>\$</u>	62,073	\$	151,700	\$	193,139	
Stock and incentive plan compensation	22,321		18,479		43,519		33,863	
Amortization of acquired intangible assets	7,971		10,122		15,987		20,053	
Campus consolidation costs	7	7	(5)		67		14	
Contingent consideration fair value adjustments	_	-	100		_		100	
Non-recurring fees	155	5			2,633			
Gain on sale of assets	_	-	_		_		(6,254)	
Strategic collaboration and license costs	10,000	)	38,191		15,413		66,191	
Investment in equity securities - unrealized (gain) loss <sup>(a)</sup>	(14,531	1)	22,537		331		(38,167)	
Acquisition, integration and divestiture-related costs	22,921		821		27,672		1,609	
Other	1,231		679		(3,221)		1,468	
Income tax effect of non-GAAP adjustments <sup>(b)</sup>	(18,206	5)	(26,158)		(34,002)		(26,859)	
Adjusted net income	\$ 110,624	\$	126,839	\$	220,099	\$	245,157	
Adjusted net income, as a percentage of revenues	29.3	3%	32.2%		29.3%	_	32.1%	

	Three Months Ended June 30,				led			
		2025		2024		2025		2024
Net income per share - diluted	\$	1.12	\$	0.88	\$	2.14	\$	2.74
Stock and incentive plan compensation		0.32		0.26		0.61		0.48
Amortization of acquired intangible assets		0.11		0.14		0.23		0.28
Campus consolidation costs		0.00		(0.00)		0.00		0.00
Contingent consideration fair value adjustments		_		0.00		_		0.00
Non-recurring fees		0.00		_		0.04		_
Gain on sale of assets		_		_		_		(0.09)
Strategic collaboration and license costs		0.14		0.54		0.22		0.94
Investment in equity securities - unrealized (gain) loss <sup>(a)</sup>		(0.21)		0.32		0.00		(0.54)
Acquisition, integration and divestiture-related costs		0.33		0.01		0.39		0.02
Other		0.02		0.01		(0.05)		0.02
Income tax effect of non-GAAP adjustments <sup>(b)</sup>		(0.26)		(0.36)		(0.48)		(0.37)
Adjusted net income per share - diluted <sup>(c)</sup>	\$	1.57	\$	1.80	\$	3.10	\$	3.48
Weighted-average common shares outstanding - diluted		70,312		70,601	_	70,896		70,364

- (a) Non-GAAP amount excludes a gain of \$42 from the change in value of other assets for the three and six months ended June 30, 2025.
- (b) 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.
- (c) Amounts may not add due to rounding.

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

(in thousands, except per share and percent data – unaudited)

	Three Months Ended June 30,			Six Month June			ded
	2025		2024		2025		2024
Operating income	\$ 87,966	\$	102,729	\$	190,033	\$	209,364
Stock and incentive plan compensation	22,321		18,479		43,519		33,863
Amortization of acquired intangible assets	7,971		10,122		15,987		20,053
Campus consolidation costs	7		(5)		67		14
Contingent consideration fair value adjustments	_		100		_		100
Non-recurring fees	155		_		2,633		_
Gain on sale of assets	_		_		_		(6,254)
Strategic collaboration and license costs	10,000		38,191		15,413		66,191
Acquisition, integration and divestiture-related costs	22,921		821		27,672		1,609
Other	1,231		679		1,506		1,468
Adjusted operating income	\$ 152,572	\$	171,116	\$	296,830	\$	326,408
Adjusted operating income, as a percentage of revenues	40.4%		43.4%		39.5%		42.7%

# **Reconciliation of Free Cash Flow**

(in thousands – unaudited)

	Three Months Ended June 30,			Six Months I June 30				
	 2025		2024		2025		2024	
Net cash provided by operating activities	\$ 87,106	\$	84,720	\$	194,669	\$	211,958	
Capital expenditures	(7,961)		(11,175)		(16,679)		(19,448)	
Free cash flow	\$ 79,145	\$	73,545	\$	177,990	\$	192,510	
Net cash used in investing activities	\$ (232,472)	\$	(45,086)	\$	(296,190)	\$	(151,615)	
Net cash (used in) provided by financing activities	\$ (98,413)	\$	99	\$	(116,632)	\$	(16,746)	

# **Condensed Consolidated Balance Sheets**

(in thousands – unaudited)

	<u></u>	June 30, 2025	1	December 31, 2024
Assets		_		
Current assets:				
Cash and cash equivalents	\$	695,572	\$	912,814
Accounts receivable, net		336,579		321,258
Inventory		62,157		68,025
Other current assets		34,093		24,536
Assets held for sale		73,415		<u> </u>
Total current assets		1,201,816		1,326,633
Investment in equity securities		45,068		39,489
Property, plant and equipment, net		157,726		176,798
Intangibles, net		359,946		161,761
Goodwill		176,869		61,189
Deferred tax assets, net		138,262		170,233
Other long-term assets		36,390		44,237
Total assets	\$	2,116,077	\$	1,980,340
Liabilities and Stockholders' Equity				
Current liabilities:				
Current portion of long-term debt and other borrowings	\$	796	\$	974
Accounts payable		40,891		34,560
Accrued expenses and other liabilities		208,600		204,992
Liabilities held for sale		29,845		_
Total current liabilities		280,132		240,526
Asset retirement obligations		136		23,344
Long-term debt and other borrowings, net of current portion		566,847		565,279
Other long-term liabilities		102,179		63,180
Total liabilities		949,294		892,329
Total stockholders' equity		1,166,783		1,088,011
Total liabilities and stockholders' equity	\$	2,116,077	\$	1,980,340

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# Lantheus Announces FDA Acceptance of NDA for New Formulation for Market-Leading PSMA PET Imaging Agent

Designed to expand PSMA PET imaging access for patients by increasing batch size by ~50% and enhancing supply resilience PDUFA date set for March 6, 2026

BEDFORD, Mass., August 6, 2025 – Lantheus Holdings, Inc. ("Lantheus") (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that the Food and Drug Administration (FDA) has accepted a New Drug Application (NDA) for a new formulation of its F 18 PSMA imaging agent filed by its affiliate, Aphelion. The FDA has set an action date goal of March 6, 2026 under the Prescription Drug User Fee Act (PDUFA).

This NDA acceptance builds on the success of Lantheus' market-leading PSMA PET imaging agent, PYLARIFY, which has demonstrated high diagnostic performance and meaningful impact on clinical decision making. If approved, we expect that this new formulation will offer an efficacy consistent with the market-leading PSMA PET agent, PYLARIFY, which has demonstrated an 86% median true-positive rate based on three independent readers in a study of patients with recurrent prostate cancer based on rising PSA after therapy. <sup>1</sup>

"We are pleased the FDA accepted Aphelion's NDA for the new piflufolastat F 18 formulation, which we expect will improve patient access due to a significant increase in the number of doses per batch," said Brian Markison, CEO, Lantheus. "This formulation is a natural next step in our commitment to advancing PSMA imaging. There is a growing burden of prostate cancer in the U.S. and a clear need for accurate and early detection. Building on PYLARIFY's proven performance and accuracy, Lantheus is well-positioned for continued leadership in prostate cancer imaging."

This new formulation optimizes the manufacturing process and is expected to increase batch size by ~50%, allowing Lantheus to serve significantly more patients while maintaining the same high standards that has made PYLARIFY the trusted choice for providers. The new formulation increases the radioactive concentration of the agent and has the potential to expand patient access in new geographic locations.

"We have reached a key milestone and delivered on our commitment to advance prostate cancer imaging through sustainable innovation," said Paul Blanchfield, President, Lantheus. "By enhancing the efficiency of production, we expect to improve patient access, streamline operations, and support the broader healthcare system's ability to deliver timely diagnostic imaging."

# **About Prostate Cancer**

In the U.S., prostate cancer is the second most frequently diagnosed cancer and fifth-leading cause of cancer-related deaths among men globally. For 2025, estimates suggest nearly 315,000 new cases and

more than 35,000 deaths.<sup>2</sup> Projections indicate a significant increase in prostate cancer incidence, with annual cases expected to nearly double to 2.9 million by 2040.<sup>3</sup> This is largely attributed to aging populations and increased life expectancy, particularly in low- and middle-income countries where healthcare access and early detection may be limited.

# About PYLARIFY® (piflufolastat F 18) Injection

PYLARIFY® (piflufolastat F 18) injection (also known as <sup>18</sup>F-DCFPyL or PyL) is a fluorinated small molecule PSMA-targeted PET imaging agent that enables visualization of lymph nodes, bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer. For men with prostate cancer, PYLARIFY PET combines the accuracy of PET imaging, the precision of PSMA targeting and the clarity of an F 18 radioisotope for superior diagnostic performance. The recommended PYLARIFY dose is 333 MBq (9 mCi) with an acceptable range of 296 MBq to 370 MBq (8 mCi to 10 mCi), administered as a bolus intravenous injection.<sup>3-9</sup>

PYLARIFY has made a profound impact on the lives of patients battling prostate cancer. It is the number one ordered PSMA PET imaging agent in the U.S., and is a proven diagnostic backed by real-world experience, including in over 500,000 scans across 48 states, Puerto Rico and Washington, D.C.

# PYLARIFY® (piflufolastat F 18) Injection

# Indication

PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- · with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

# **Important Safety Information**

#### Contraindications

None.

# **Warnings and Precautions**

# **Risk of Image Misinterpretation**

Imaging interpretation errors can occur with PYLARIFY imaging. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of PYLARIFY for imaging of patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

# **Hypersensitivity Reactions**

Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

#### **Radiation Risks**

Diagnostic radiopharmaceuticals, including PYLARIFY, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

#### **Adverse Reactions**

The most frequently reported adverse reactions were headaches, dysgeusia and fatigue, occurring at rate of ≤2% during clinical studies with PYLARIFY. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reactions.

# **Drug interactions**

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, may result in changes in uptake of PYLARIFY in prostate cancer. The effect of these therapies on performance of PYLARIFY PET has not been established.

To report suspected adverse reactions for PYLARIFY, call 1-800-362-2668 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Please read the accompanying full Prescribing Information also available at PYLARIFY.com.

# Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains "forward-looking statements" that are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements relating to the potential FDA approval of the NDA for a new formulation of piflufolastat F18, the Company's F-18 based PET imaging agent and statements regarding Lantheus' expectations, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements may be identified by their use of terms such as "aim," "designed," "expect," "expected," "will" and other similar terms. Such forward-looking statements 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, including our ability to obtain FDA approval for our new formulation of PYLARIFY, to complete the technology transfer across our PET manufacturing facilities network for such new formulation, and to obtain adequate coding, coverage and payment, as well as 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).

# **About Lantheus**

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 New Jersey, Canada, Germany, Sweden and Switzerland, Lantheus has been providing radiopharmaceutical solutions for nearly 70 years. For more information, visit www.lantheus.com.

<sup>1</sup>Morris MJ, et al; CONDOR Study Group. Diagnostic Performance of 18F-DCFPyL-PET/CT in Men with Biochemically Recurrent Prostate Cancer: Results from the CONDOR Phase III, Multicenter Study. Clin Cancer Res. 2021 Jul 1;27(13):3674-3682. doi: 10.1158/1078-0432.CCR-20-4573. Epub 2021 Feb 23. PMID: 33622706; PMCID: PMC8382991.

<sup>2</sup>American Cancer Society. *Cancer Facts & Figures 2025*. Atlanta: American Cancer Society; 2025. Available at https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2025-cancer-facts-figures.html <sup>3</sup>Harris E. Prostate Cancer Cases Might Rise to 3 Million Globally by 2040. *JAMA*. 2024;331(20):1698. doi:10.1001/jama.2024.6729

<sup>4</sup>PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company.

<sup>5</sup>Data on file. Bedford, MA: Progenics Pharmaceuticals, Inc.; 2024.

<sup>6</sup>Mena E, Lindenberg ML, Turkbey IB, et al. *18*F-DCFPyL PET/CT imaging in patients with biochemically recurrent prostate cancer after primary local therapy. *J Nucl Med*. 2020;61(6):881-889.

<sup>7</sup>Werner RA, Derlin T, Lapa C, et al. *18*F-labeled, PSMA-targeted radiotracers: leveraging the advantages of radiofluorination for prostate cancer molecular imaging. *Theranostics*. 2020;10(1):1-16.

<sup>8</sup>Alipour R, Azad A, Hofman MS. Guiding management of therapy in prostate cancer: time to switch from conventional imaging to PSMA PET? *Ther Adv Med Oncol*. 2019;11:1-14.

<sup>9</sup>Petersen LJ, Zacho HD. PSMA PET for primary lymph node staging of intermediate and high-risk prostate cancer: an expedited systematic review. *Cancer Imaging*. 2020;20(1):10.

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