
**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): September 30, 2021

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.)

331 Treble Cove Road, North Billerica, MA
(Address of principal executive offices)

01862
(Zip Code)

Registrant's telephone number, including area code: (978) 671-8001

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- 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 Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.01 per share	LNTH	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2021, Lantheus Holdings, Inc. (the “Company”) announced via press release its financial results as of and for the three and nine months ended September 30, 2021. 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, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Press release of Lantheus Holdings, Inc. dated November 4, 2021, entitled "Lantheus Holdings, Inc. Reports Third Quarter 2021 Financial Results"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Exhibit 99.1 attached hereto is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, 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: Senior Vice President and General Counsel

Date: November 4, 2021



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North Billerica, MA 01862

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Lantheus Holdings, Inc. Reports Third Quarter 2021 Financial Results

- **Worldwide revenue of \$102.1 million for the third quarter 2021, representing an increase of 15.3% from the prior year period**
- **GAAP net loss of \$13.4 million for the third quarter 2021, compared to GAAP net loss of \$6.4 million in the prior year period**
- **GAAP fully diluted net loss of \$0.20 for the third quarter 2021, compared to GAAP fully diluted net loss of \$0.10 in the prior year period; adjusted fully diluted EPS of \$0.08 for the third quarter 2021, compared to adjusted fully diluted EPS of \$0.04 in the prior year period**
- **Net cash provided by operating activities was \$4.3 million for the third quarter 2021. Free cash flow was \$1.9 million in the third quarter 2021**
- **The Company reported that, following an interim analysis of the ongoing ARROW Phase 2 study of 1095, a PSMA-targeted therapeutic, in metastatic castration resistant prostate cancer patients, the Independent Data Monitoring Committee recommended the study continue without modifications**
- **The Company provides fourth quarter 2021 revenue and adjusted diluted earnings per share guidance; increases full year guidance**

NORTH BILLERICA, MA., November 4, 2021 - [Lantheus Holdings, Inc.](https://www.lantheus.com) (NASDAQ: LNTH) (Lantheus), an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to find, fight and follow serious medical conditions, today reported financial results for its third quarter ended September 30, 2021.

The Company's worldwide revenue for the third quarter of 2021 totaled \$102.1 million, compared with \$88.5 million for the third quarter of 2020, representing an increase of 15.3% from the prior year period.

The Company's third quarter 2021 GAAP net loss was \$13.4 million, or \$0.20 per fully diluted share, as compared to GAAP net loss of \$6.4 million, or \$0.10 per fully diluted share for the third quarter of 2020.

The Company's third quarter 2021 adjusted fully diluted earnings per share were \$0.08, as compared to \$0.04 for the third quarter of 2020, representing an increase of 127.4% from the prior year period.

Lastly, net cash provided by operating activities was \$4.3 million for the third quarter 2021. Free Cash Flow was \$1.9 million in the third quarter of 2021, representing a decrease of approximately \$2.9 million from the prior year period.

"We delivered a strong quarter, with revenue up 15% year-over-year, highlighted by the robust adoption of PYLARIFY, the first and only commercially available PSMA PET imaging agent," said Mary Anne Heino, President and CEO. "Although COVID-19 continued to impact some aspects of our business, we were able to grow our three largest products – DEFINITY, TechnoLite and PYLARIFY. We look forward to driving sustainable growth across our portfolio of diagnostic and therapeutic solutions as we find, fight and follow diseases to deliver better patient outcomes."

"We are pleased with the first full quarter of PYLARIFY sales and continue to invest in our commercial launch, including in manufacturing capacity, to meet the increasing demand for this game changing product. We completed the build-out of our commercial infrastructure, which represents the industry's largest PSMA PET-dedicated sales and market access teams," said Paul Blanchfield, Chief Commercial Officer. "We remain focused on fostering customer adoption and expanding our geographic and market access coverage in service of our customers and the U.S. Prostate Cancer community."

Outlook

The Company updates its guidance for full year 2021 and offers the following guidance for the fourth quarter.

	Q4 Guidance Issued November 4, 2021	Previous Guidance Issued July 28, 2021
Q4 FY 2021 Revenue	\$110 million - \$115 million	N/A
Q4 FY 2021 Adjusted Diluted EPS	\$0.15 - \$0.18	N/A
	FY Guidance Updated November 4, 2021	FY Guidance Issued July 28, 2021
FY 2021 Revenue	\$405 million - \$410 million	\$395 million - \$402 million
FY 2021 Adjusted Diluted EPS	\$0.40 - \$0.43	\$0.38 - \$0.42

On a forward-looking basis, the Company does not provide GAAP income per common share guidance or a reconciliation of adjusted fully diluted EPS to GAAP income per common share because the Company is unable to predict with reasonable certainty business development and acquisition related expenses, purchase accounting fair value adjustments (including liability accruals relating to the contingent value rights issued as part of the Progenics Pharmaceuticals, Inc. acquisition), 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.

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.

Conference Call and Webcast

As previously announced, the Company will host a conference call and webcast on Thursday, November 4, 2021 at 8:00 a.m. ET. To access the live conference call via telephone, please dial 1-866-498-8390 (U.S. callers) or 1-678-509-7599 (international callers) and provide passcode 6775813. A live webcast will be available in the Investors section of the Company's website at www.lantheus.com.

A replay of the audio webcast will be available in the Investors section of our website at www.lantheus.com approximately two hours after completion of the call and will be archived for 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 Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB and an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find Fight and Follow[®] serious medical conditions. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY[®] Vial for (Perflutren Lipid Microsphere) Injectable Suspension; PYLARIFY[®], a PSMA PET imaging agent for the detection of suspected recurrent or metastatic prostate cancer; TechnoLite[®] (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; AZEDRA[®] for the treatment of certain rare neuroendocrine tumors; and RELISTOR[®] for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies, Inc. The Company is headquartered in North Billerica, Massachusetts with offices in New York, New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

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; 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 “believe,” “could,” “estimate,” “expect,” “look forward to,” “may,” “plan,” “predict,” “target,” “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. 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) the impact of the global COVID-19 pandemic on our business, financial conditions and prospects; (ii) continued market expansion and penetration for our commercial products, particularly DEFINITY, in the face of segment competition and potential generic competition, including as a result of patent and regulatory exclusivity expirations; (iii) our ability to successfully launch PYLARIFY as a commercial product, including (A) our ability to obtain U.S. Food and Drug Administration approval for additional PET manufacturing facilities (“PMFs”) that could manufacture PYLARIFY, (B) the ability of those PMFs to supply PYLARIFY to customers, and (C) our ability to sell PYLARIFY to customers; (iv) the global Molybdenum-99 supply; (v) our products manufactured at Jubilant HollisterStier and our modified formulation of DEFINITY (“DEFINITY RT”) to be commercially manufactured at Samsung Biologics, including our ability to renew, modify or replace those agreements as may be necessary; (vi) the continued integration of the Progenics products and product candidate portfolio into our business following the Progenics Acquisition; (vii) our ability to use in-house manufacturing capacity; (viii) our ability to successfully launch aPROMISE, also referred to as PYLARIFY AI, as a commercial product; (ix) the potential reclassification by the FDA of certain of our products and product candidates from drugs to devices with the expense, complexity and potentially more limited competitive protection such reclassification could cause; (x) the efforts and timing for clinical development of our product candidates and new clinical applications for our products, in each case, that we or our strategic partners may develop, including 1095 and flurpiridaz F 18; (xi) our ability to develop highly contextualized assessments of disease burden using artificial intelligence (“AI”); and (xii) 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 -

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Lantheus Holdings, Inc.
Consolidated Statements of Operations
(in thousands, except per share data – unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues	\$ 102,073	\$ 88,544	\$ 295,646	\$ 245,258
Cost of goods sold	59,404	52,284	165,859	145,148
Gross profit	<u>42,669</u>	<u>36,260</u>	<u>129,787</u>	<u>100,110</u>
Operating expenses				
Sales and marketing	17,195	11,609	48,999	28,044
General and administrative	28,550	18,217	87,865	55,586
Research and development	11,252	11,684	33,673	20,150
Total operating expenses	<u>56,997</u>	<u>41,510</u>	<u>170,537</u>	<u>103,780</u>
Gain on sale of assets	—	—	15,263	—
Operating loss	<u>(14,328)</u>	<u>(5,250)</u>	<u>(25,487)</u>	<u>(3,670)</u>
Interest expense	1,569	2,808	6,224	6,668
Gain on extinguishment of debt	—	—	(889)	—
Other loss (income)	3,940	(596)	3,209	(1,702)
Loss before income taxes	<u>(19,837)</u>	<u>(7,462)</u>	<u>(34,031)</u>	<u>(8,636)</u>
Income tax (benefit) expense	(6,422)	(1,076)	(2,967)	1,425
Net loss	<u>\$ (13,415)</u>	<u>\$ (6,386)</u>	<u>\$ (31,064)</u>	<u>\$ (10,061)</u>
Net loss per common share:				
Basic	<u>\$ (0.20)</u>	<u>\$ (0.10)</u>	<u>\$ (0.46)</u>	<u>\$ (0.20)</u>
Diluted	<u>\$ (0.20)</u>	<u>\$ (0.10)</u>	<u>\$ (0.46)</u>	<u>\$ (0.20)</u>
Weighted-average common shares outstanding:				
Basic	<u>67,623</u>	<u>66,820</u>	<u>67,409</u>	<u>49,858</u>
Diluted	<u>67,623</u>	<u>66,820</u>	<u>67,409</u>	<u>49,858</u>

Lantheus Holdings, Inc.
Consolidated Revenues Analysis
(in thousands – unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020 ⁽¹⁾	% Change	2021	2020 ⁽¹⁾	% Change
DEFINITY	\$ 57,636	\$ 50,359	14.5 %	\$ 173,448	\$ 139,989	23.9 %
TechneLite	22,680	21,113	7.4 %	69,252	62,560	10.7 %
Other precision diagnostics	7,563	8,585	(11.9)%	21,289	28,782	(26.0)%
Total precision diagnostics	87,879	80,057	9.8 %	263,989	231,331	14.1 %
Radiopharmaceutical oncology	8,890	3,323	167.5 %	13,203	7,474	76.7 %
Strategic partnerships and other	5,304	5,164	2.7 %	18,454	6,453	186.0 %
Total revenues	\$ 102,073	\$ 88,544	15.3 %	\$ 295,646	\$ 245,258	20.5 %

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1. The Company reclassified rebates and allowances of \$5.5 million and \$13.8 million within each product category, which included \$5.1 million and \$12.6 million for DEFINITY, \$0.3 million and \$0.9 million for TechneLite and \$0.1 million and \$0.2 million for other precision diagnostics, for the three and nine months ended September 30, 2020, respectively.

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,	
	2021	2020	2021	2020
Net loss	\$ (13,415)	\$ (6,386)	\$ (31,064)	\$ (10,061)
Stock and incentive plan compensation	3,867	3,992	11,772	10,452
Amortization of acquired intangible assets	8,374	4,768	19,133	6,087
Acquired debt fair value adjustment	—	(385)	(307)	(385)
Contingent consideration fair value adjustments	2,600	800	28,500	800
Non-recurring refinancing related fees	—	—	—	460
Non-recurring severance related fees	(6)	—	522	—
Extinguishment of debt	—	—	(889)	—
Gain on sale of assets	—	—	(15,263)	—
Integration costs	63	855	93	4,428
Acquisition-related costs	62	1,593	726	10,522
Impairment of long-lived assets	9,540	—	9,540	7,275
Other	7	—	60	(75)
Income tax effect of non-GAAP adjustments ^(a)	(5,411)	(2,819)	(6,059)	(8,265)
Adjusted net income	\$ 5,681	\$ 2,418	\$ 16,764	\$ 21,238
Adjusted net income, as a percentage of revenues	5.6 %	2.7 %	5.7 %	8.7 %

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss per share - diluted	\$ (0.20)	\$ (0.10)	\$ (0.46)	\$ (0.20)
Stock and incentive plan compensation	0.05	0.06	0.18	0.21
Amortization of acquired intangible assets	0.12	0.08	0.28	0.12
Acquired debt fair value adjustment	—	(0.01)	(0.01)	(0.01)
Contingent consideration fair value adjustments	0.04	0.01	0.42	0.01
Non-recurring refinancing related fees	—	—	—	0.01
Non-recurring severance related fees	—	—	0.01	—
Extinguishment of debt	—	—	(0.01)	—
Gain on sale of assets	—	—	(0.23)	—
Integration costs	—	0.01	—	0.09
Acquisition-related costs	0.01	0.02	0.01	0.21
Impairment of long-lived assets	0.14	—	0.14	0.14
Other	—	—	—	—
Income tax effect of non-GAAP adjustments ^(a)	(0.08)	(0.03)	(0.09)	(0.16)
Adjusted net income per share - diluted	\$ 0.08	\$ 0.04	\$ 0.24	\$ 0.42
Weighted-average common shares outstanding - diluted	69,237	67,006	68,674	50,210

- (a) The income tax effect of the adjustments between GAAP net loss and non-GAAP adjusted net income 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 Free Cash Flow
(in thousands – unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net cash provided by operating activities	\$ 4,340	\$ 8,575	\$ 40,027	\$ 15,827
Capital expenditures	(2,420)	(3,736)	(7,596)	(8,689)
Free cash flow	<u>\$ 1,920</u>	<u>\$ 4,839</u>	<u>\$ 32,431</u>	<u>\$ 7,138</u>
Net cash (used in) provided by investing activities	<u>\$ (2,420)</u>	<u>\$ (3,736)</u>	<u>\$ 8,227</u>	<u>\$ (1,127)</u>
Net cash used in financing activities	<u>\$ (1,726)</u>	<u>\$ (7,270)</u>	<u>\$ (37,232)</u>	<u>\$ (17,488)</u>

Lantheus Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands – unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 91,475	\$ 79,612
Accounts receivable, net	64,054	54,002
Inventory	33,949	35,744
Other current assets	12,043	9,625
Assets held for sale	—	5,242
Total current assets	201,521	184,225
Property, plant and equipment, net	116,441	120,171
Intangibles, net	356,883	376,012
Goodwill	61,189	58,632
Deferred tax assets, net	66,493	70,147
Other long-term assets	45,289	60,634
Total assets	\$ 847,816	\$ 869,821
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	\$ 10,356	\$ 20,701
Accounts payable	20,508	16,284
Accrued expenses and other liabilities	46,039	41,726
Liabilities held for sale	—	1,793
Total current liabilities	76,903	80,504
Asset retirement obligations	15,185	14,020
Long-term debt, net and other borrowings	166,741	197,699
Other long-term liabilities	89,643	63,393
Total liabilities	348,472	355,616
Total stockholders' equity	499,344	514,205
Total liabilities and stockholders' equity	\$ 847,816	\$ 869,821

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