
**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): December 31, 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 February 24, 2022, Lantheus Holdings, Inc. (the “Company”) announced via press release its financial results as of and for the three and twelve months ended December 31, 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 December 31, 2021, entitled "Lantheus Holdings, Inc. Reports Fourth Quarter and Full Year 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: February 24, 2022



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North Billerica, MA 01862

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Lantheus Holdings, Inc. Reports Fourth Quarter and Full Year 2021 Financial Results

- **Worldwide revenue of \$129.6 million and \$425.2 million for the fourth quarter and full year 2021, representing an increase of 37.6% and an increase of 25.3% over the prior year period, respectively**
- **GAAP net loss of \$40.2 million and \$71.3 million for the fourth quarter and full year 2021, compared to GAAP net loss of \$3.4 million and \$13.5 million in the prior year period; adjusted net income of \$17.2 million and \$34.0 million for the fourth quarter and full year 2021, compared to adjusted net income of \$4.6 million and \$25.8 million in the prior year period**
- **GAAP fully diluted net loss of \$0.59 and \$1.06 for the fourth quarter and full year 2021, compared to GAAP fully diluted net loss of \$0.05 and \$0.25 in the prior year period; adjusted fully diluted EPS of \$0.25 and \$0.49 for the fourth quarter and full year 2021, compared to adjusted fully diluted EPS of \$0.07 and \$0.47 in the prior year period**
- **Net cash provided by operating activities was \$13.9 million and \$53.9 million for the fourth quarter and full year 2021. Free cash flow of \$9.3 million and \$41.8 million for the fourth quarter and full year 2021, compared to free cash flow of \$(3.2) million and \$3.9 million for the fourth quarter and full year 2020**
- **The Company provides first quarter and full year 2022 revenue and adjusted diluted earnings per share guidance**

NORTH BILLERICA, MA., February 24, 2022 - [Lantheus Holdings, Inc.](#) (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 fourth quarter and full year ended December 31, 2021.

The Company's worldwide revenue for the fourth quarter of 2021 totaled \$129.6 million, compared with \$94.2 million for the fourth quarter of 2020, representing an increase of 37.6% over the prior year period. Full year 2021 worldwide revenues were \$425.2 million, compared with \$339.4 million for the full year 2020, representing an increase of 25.3% over the prior year period.

The Company's fourth quarter 2021 net loss was \$40.2 million, or \$0.59 per fully diluted share, as compared to net loss of \$3.4 million, or \$0.05 per fully diluted share for the fourth quarter of 2020. Full year 2021 net loss was \$71.3 million, or \$1.06 per fully diluted share, as compared to net loss of \$13.5 million, or \$0.25 per fully diluted share for the full year 2020.

The Company's fourth quarter 2021 adjusted fully diluted earnings per share were \$0.25, as compared to \$0.07 for the fourth quarter of 2020, representing an increase of 263.5% over the prior year period. The Company's full year 2021 adjusted fully diluted earnings per share were \$0.49, as compared to \$0.47 for the full year 2020, representing an increase of 4.0% over the prior year period.

Lastly, net cash provided by operating activities was \$13.9 million and \$53.9 million for the fourth quarter and full year 2021. Free Cash Flow was \$9.3 million for the fourth quarter of 2021, as compared to \$(3.2) million for the fourth quarter of 2020, representing an increase of approximately \$12.5 million from the prior year period. Full year 2021 free cash flow was \$41.8 million, as compared to \$3.9 million for the full year 2020, representing an increase of approximately \$37.9 million from the prior year period.

"Lantheus delivered another strong quarter and full year, highlighted by revenue performance which increased 38% and 25%, respectively," said Mary Anne Heino, President and CEO. "We successfully launched PYLARIFY, which we believe is the best-in-class PSMA PET imaging agent for prostate cancer, maintained our revenue growth and market leadership for DEFINITY, and delivered top quartile returns for our shareholders, even amidst a backdrop of macro external challenges. This year is off to a similarly productive start as we received FDA approval for our on-site manufacturing facility for DEFINITY. In 2022, we will continue to advance our purpose to Find, Fight and Follow serious medical conditions to improve patient outcomes, and continue to drive revenue growth and shareholder value."

Outlook

The Company updates its guidance for the first quarter and full year 2022 is as follows:

Guidance Issued February 24, 2022	
Q1 FY 2022 Revenue	\$160 million - \$170 million
Q1 FY 2022 Adjusted Fully Diluted EPS	\$0.45 - \$0.50
Guidance Issued February 24, 2022	
FY 2022 Revenue	\$685 million - \$710 million
FY 2022 Adjusted Fully Diluted EPS	\$1.95 - \$2.05

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, February 24, 2022 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 4894137. 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; PYLARIFY AI[™], an artificial intelligence platform that assists in the evaluation of PSMA PET images; 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 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,” “commit,” “advance,” “continue” 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) continued market expansion and penetration for our established commercial products, particularly DEFINITY, in the face of segment competition and potential generic competition, including as a result of patent and regulatory exclusivity expirations; (ii) our ability to successfully launch PYLARIFY as a commercial product, including (A) our ability to obtain United States Food and Drug Administration (“FDA”) approval for additional positron emission tomography (“PET”) manufacturing facilities (“PMFs”) to manufacture PYLARIFY, (B) the ability of those PMFs to manufacture PYLARIFY, (C) our ability to sell PYLARIFY to customers, and (D) our ability to obtain and maintain adequate coding, coverage and payment for PYLARIFY; (iii) the global Molybdenum-99 supply; (iv) our ability to use in-house manufacturing capacity; (v) our ability to successfully launch PYLARIFY AI as a commercial product; (vi) our ability to have products manufactured at Jubilant HollisterStier and our modified formulation of DEFINITY at Samsung Biologics, including our ability to renew, modify or replace the agreements related to such manufacturing services on commercially reasonable terms, as may be necessary; (vii) the continuing impact of the global COVID-19 pandemic on our business, financial conditions and prospects; (viii) the efforts and timing for clinical development of our product candidates and new clinical applications for our products, in each case, that we may develop, including 1095 and LMI 1195 or that our strategic partners may develop, including flurpiridaz fluorine-18; (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 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 -

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues	\$ 129,562	\$ 94,152	\$ 425,208	\$ 339,410
Cost of goods sold	71,654	55,501	237,513	200,649
Gross profit	<u>57,908</u>	<u>38,651</u>	<u>187,695</u>	<u>138,761</u>
Operating expenses				
Sales and marketing	19,423	12,857	68,422	40,901
General and administrative	62,530	13,684	150,395	69,270
Research and development	11,293	12,638	44,966	32,788
Total operating expenses	<u>93,246</u>	<u>39,179</u>	<u>263,783</u>	<u>142,959</u>
Gain on sale of assets	—	—	15,263	—
Operating loss	<u>(35,338)</u>	<u>(528)</u>	<u>(60,825)</u>	<u>(4,198)</u>
Interest expense	1,528	2,811	7,752	9,479
Gain on extinguishment of debt	—	—	(889)	—
Other loss (income)	4,141	(496)	7,350	(2,198)
Loss before income taxes	<u>(41,007)</u>	<u>(2,843)</u>	<u>(75,038)</u>	<u>(11,479)</u>
Income tax (benefit) expense	(792)	569	(3,759)	1,994
Net loss	<u>\$ (40,215)</u>	<u>\$ (3,412)</u>	<u>\$ (71,279)</u>	<u>\$ (13,473)</u>
Net loss per common share:				
Basic	<u>\$ (0.59)</u>	<u>\$ (0.05)</u>	<u>\$ (1.06)</u>	<u>\$ (0.25)</u>
Diluted	<u>\$ (0.59)</u>	<u>\$ (0.05)</u>	<u>\$ (1.06)</u>	<u>\$ (0.25)</u>
Weighted-average common shares outstanding:				
Basic	<u>67,713</u>	<u>66,870</u>	<u>67,486</u>	<u>54,134</u>
Diluted	<u>67,713</u>	<u>66,870</u>	<u>67,486</u>	<u>54,134</u>

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

	Three Months Ended December 31,			Year Ended December 31,		
	2021	2020 ⁽¹⁾	% Change	2021	2020 ⁽¹⁾	% Change
DEFINITY	\$ 59,311	\$ 55,876	6.1 %	\$ 232,759	\$ 195,865	18.8 %
TechneLite	22,041	22,385	(1.5)%	91,293	84,945	7.5 %
Other precision diagnostics	5,684	8,042	(29.3)%	26,973	36,824	(26.8)%
Total precision diagnostics	87,036	86,303	0.8 %	351,025	317,634	10.5 %
PYLARIFY	35,417	—	N/A	43,414	—	N/A
Other radiopharmaceutical oncology	267	2,548	(89.5)%	5,473	10,022	(45.4)%
Total radiopharmaceutical oncology	35,684	2,548	1300.5 %	48,887	10,022	387.8 %
Strategic Partnerships and other revenue	6,842	5,301	29.1 %	25,296	11,754	115.2 %
Total revenues	\$ 129,562	\$ 94,152	37.6 %	\$ 425,208	\$ 339,410	25.3 %

1. The Company reclassified aggregate rebates and allowances of \$5.3 million and \$19.1 million for the three months and year ended December 31, 2020, respectively, which included \$4.9 million and \$17.5 million for DEFINITY, \$0.4 million and \$1.3 million for TechneLite and \$0.1 million and \$0.3 million for other precision diagnostics.

Lantheus Holdings, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures

(in thousands, except per share data – unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net loss	\$ (40,215)	\$ (3,412)	\$ (71,279)	\$ (13,473)
Stock and incentive plan compensation	4,162	3,623	15,934	14,075
Amortization of acquired intangible assets	8,373	4,683	27,506	10,770
Acquired debt fair value adjustment	—	(326)	(307)	(711)
Contingent consideration fair value adjustments	43,900	(2,800)	72,400	(2,000)
Non-recurring refinancing related fees	—	—	—	460
Non-recurring severance related fees	—	904	522	904
Non-recurring fees	818	—	818	—
Extinguishment of debt	—	—	(889)	—
Gain on sale of assets	—	—	(15,263)	—
Integration costs	9	2,772	102	7,201
Acquisition-related costs	823	1,334	1,549	11,856
Impairment of long-lived assets	189	2,660	9,729	9,935
ARO Acceleration	5,259	—	5,259	—
Other	2	35	62	(40)
Income tax effect of non-GAAP adjustments ^(a)	(6,079)	(4,886)	(12,138)	(13,152)
Adjusted net income	\$ 17,241	\$ 4,587	\$ 34,005	\$ 25,825
Adjusted net income, as a percentage of revenues	13.3 %	4.9 %	8.0 %	7.6 %

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net loss per share - diluted	\$ (0.59)	\$ (0.05)	\$ (1.06)	\$ (0.25)
Stock and incentive plan compensation	0.06	0.05	0.24	0.26
Amortization of acquired intangible assets	0.13	0.08	0.41	0.20
Acquired debt fair value adjustment	—	—	(0.01)	(0.01)
Contingent consideration fair value adjustments	0.63	(0.04)	1.05	(0.05)
Non-recurring refinancing related fees	—	—	—	0.01
Non-recurring severance related fees	—	0.02	0.01	0.02
Non-recurring fees	0.01	—	0.01	—
Extinguishment of debt	—	—	(0.01)	—
Gain on sale of assets	—	—	(0.23)	—
Integration costs	—	0.04	—	0.13
Acquisition-related costs	0.01	0.01	0.02	0.22
Impairment of long-lived assets	—	0.04	0.14	0.18
ARO Acceleration	0.08	—	0.08	—
Income tax effect of non-GAAP adjustments ^(a)	(0.08)	(0.08)	(0.16)	(0.24)
Adjusted net income per share - diluted	\$ 0.25	\$ 0.07	\$ 0.49	\$ 0.47
Weighted-average common shares outstanding - diluted	69,446	67,130	68,963	54,471

- (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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net cash provided by operating activities	\$ 13,889	\$ 569	\$ 53,916	\$ 16,396
Capital expenditures	(4,544)	(3,785)	(12,140)	(12,474)
Free cash flow	<u>\$ 9,345</u>	<u>\$ (3,216)</u>	<u>\$ 41,776</u>	<u>\$ 3,922</u>
Net cash (used in) provided by investing activities	<u>\$ (4,544)</u>	<u>\$ (3,785)</u>	<u>\$ 3,683</u>	<u>\$ (4,912)</u>
Net cash used in financing activities	<u>\$ (2,100)</u>	<u>\$ (4,373)</u>	<u>\$ (39,332)</u>	<u>\$ (21,861)</u>

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

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 98,508	\$ 79,612
Accounts receivable, net	89,336	54,002
Inventory	35,129	35,744
Other current assets	12,818	9,625
Assets held for sale	—	5,242
Total current assets	235,791	184,225
Property, plant and equipment, net	116,772	120,171
Intangibles, net	348,510	376,012
Goodwill	61,189	58,632
Deferred tax assets, net	62,764	70,147
Other long-term assets	38,758	60,634
Total assets	\$ 863,784	\$ 869,821
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	\$ 11,642	\$ 20,701
Accounts payable	20,787	16,284
Accrued expenses and other liabilities	58,068	41,726
Liabilities held for sale	—	1,793
Total current liabilities	90,497	80,504
Asset retirement obligations	20,833	14,020
Long-term debt, net and other borrowings	163,121	197,699
Other long-term liabilities	124,894	63,393
Total liabilities	399,345	355,616
Total stockholders' equity	464,439	514,205
Total liabilities and stockholders' equity	\$ 863,784	\$ 869,821

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