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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2021

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-36569

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**35-2318913**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
331 Treble Cove Road North Billerica, MA	**01862**
(Address of principal executive offices)	**(Zip Code)**

(978) 671-8001

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act) Yes ☐ No ☑

The registrant had 67,690,586 shares of common stock, $0.01 par value, outstanding as of October 28, 2021.

LANTHEUS HOLDINGS, INC.
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Lantheus Holdings, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except par value)

	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
Commitments and contingencies (See Note 19)		
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; 67,659 and 66,875 shares issued and outstanding, respectively)	677	669
Additional paid-in capital	680,819	665,530
Accumulated deficit	(181,010)	(149,946)
Accumulated other comprehensive loss	(1,142)	(2,048)
Total stockholders' equity	499,344	514,205
Total liabilities and stockholders' equity	$ 847,816	$ 869,821

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	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	42,669	36,260	129,787	100,110
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	56,997	41,510	170,537	103,780
Gain on sale of assets	—	—	15,263	—
Operating loss	(14,328)	(5,250)	(25,487)	(3,670)
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	(19,837)	(7,462)	(34,031)	(8,636)
Income tax (benefit) expense	(6,422)	(1,076)	(2,967)	1,425
Net loss	$ (13,415)	$ (6,386)	$ (31,064)	$ (10,061)
Net loss per common share:				
Basic	$ (0.20)	$ (0.10)	$ (0.46)	$ (0.20)
Diluted	$ (0.20)	$ (0.10)	$ (0.46)	$ (0.20)
Weighted-average common shares outstanding:				
Basic	67,623	66,820	67,409	49,858
Diluted	67,623	66,820	67,409	49,858

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Comprehensive Income
(Unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (13,415)	$ (6,386)	$ (31,064)	$ (10,061)
Other comprehensive (loss) income:				
Foreign currency translation	(240)	185	55	(9)
Unrealized gain (loss) on cash flow hedges, net of tax	98	(89)	851	(1,541)
Total other comprehensive (loss) income	(142)	96	906	(1,550)
Comprehensive loss	$ (13,557)	$ (6,290)	$ (30,158)	$ (11,611)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)
(in thousands)

	Nine Months Ended September 30, 2021					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2021	66,875	$ 669	$ 665,530	$ (149,946)	$ (2,048)	$ 514,205
Net income	—	—	—	9,008	—	9,008
Other comprehensive income	—	—	—	—	808	808
Stock option exercises and employee stock plan purchases	155	1	2,379	—	—	2,380
Vesting of restricted stock awards and units	489	5	(5)	—	—	—
Shares withheld to cover taxes	(85)	(1)	(1,598)	—	—	(1,599)
Stock-based compensation	—	—	3,317	—	—	3,317
Balance, March 31, 2021	67,434	$ 674	$ 669,623	$ (140,938)	$ (1,240)	$ 528,119
Net loss	—	—	—	(26,657)	—	(26,657)
Other comprehensive income	—	—	—	—	240	240
Stock option exercises and employee stock plan purchases	116	1	2,042	—	—	2,043
Vesting of restricted stock awards and units	51	1	(1)	—	—	—
Shares withheld to cover taxes	(9)	—	(193)	—	—	(193)
Stock-based compensation	—	—	4,588	—	—	4,588
Balance, June 30, 2021	67,592	$ 676	$ 676,059	$ (167,595)	$ (1,000)	$ 508,140
Net loss	—	—	—	(13,415)	—	(13,415)
Other comprehensive loss	—	—	—	—	(142)	(142)
Stock option exercises and employee stock plan purchases	48	1	960	—	—	961
Vesting of restricted stock awards and units	23	—	—	—	—	—
Shares withheld to cover taxes	(4)	—	(67)	—	—	(67)
Stock-based compensation	—	—	3,867	—	—	3,867
Balance, September 30, 2021	67,659	$ 677	$ 680,819	$ (181,010)	$ (1,142)	$ 499,344

	Nine Months Ended September 30, 2020					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2020	39,251	$ 393	$ 251,641	$ (136,473)	$ (960)	$ 114,601
Net income	—	—	—	3,337	—	3,337
Other comprehensive loss	—	—	—	—	(1,434)	(1,434)
Stock option exercises and employee stock plan purchases	33	—	366	—	—	366
Vesting of restricted stock awards and units	563	6	(6)	—	—	—
Shares withheld to cover taxes	(97)	(1)	(1,546)	—	—	(1,547)
Stock-based compensation	—	—	3,075	—	—	3,075
Balance, March 31, 2020	39,750	$ 398	$ 253,530	$ (133,136)	$ (2,394)	$ 118,398
Net loss	—	—	—	(7,012)	—	(7,012)
Other comprehensive loss	—	—	—	—	(212)	(212)
Stock option exercises and employee stock plan purchases	7	—	50	—	—	50
Vesting of restricted stock awards and units	242	2	(2)	—	—	—
Shares withheld to cover taxes	(36)	(1)	(484)	—	—	(485)
Issuance of common stock, net of $3,776 issuance costs	26,845	269	394,065	—	—	394,334
Fair value of replacement options related to pre-acquisition services	—	—	7,125	—	—	7,125
Stock-based compensation	—	—	3,385	—	—	3,385
Balance, June 30, 2020	66,808	$ 668	$ 657,669	$ (140,148)	$ (2,606)	$ 515,583
Net loss	—	—	—	(6,386)	—	(6,386)
Other comprehensive income	—	—	—	—	96	96
Stock option exercises and employee stock plan purchases	32	—	344	—	—	344
Vesting of restricted stock awards and units	13	1	(1)	—	—	—
Shares withheld to cover taxes	(3)	(1)	(49)	—	—	(50)
Stock-based compensation	—	—	3,992	—	—	3,992
Balance, September 30, 2020	66,850	$ 668	$ 661,955	$ (146,534)	$ (2,510)	$ 513,579

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (31,064)	$ (10,061)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation, amortization and accretion	30,088	16,295
Impairment of long-lived assets	9,540	7,275
Amortization of debt related costs	430	199
Changes in fair value of contingent assets and liabilities	28,500	800
Gain on extinguishment of debt	(889)	—
Provision for excess and obsolete inventory	2,317	1,870
Stock-based compensation	11,772	10,452
Gain on sale of assets	(15,263)	—
Deferred taxes	1,028	(781)
Long-term income tax receivable	3,092	(1,664)
Long-term income tax payable and other long-term liabilities	(3,617)	2,114
Other	1,724	1,034
(Decreases) increases in cash from operating assets and liabilities:		
Accounts receivable	(7,721)	(703)
Inventory	(625)	(9,593)
Other current assets	1,998	1,563
Accounts payable	4,776	3,762
Accrued expenses and other liabilities	3,941	(6,735)
Net cash provided by operating activities	40,027	15,827
Investing activities		
Capital expenditures	(7,596)	(8,689)
Proceeds from sale of assets, net	15,823	—
Lending on bridge loan	—	(10,000)
Cash acquired in acquisition of business	—	17,562
Net cash provided by (used in) investing activities	8,227	(1,127)
Financing activities		
Payments on long-term debt and other borrowings	(40,757)	(11,166)
Equity issuance costs	—	(3,777)
Deferred financing costs	—	(1,223)
Proceeds from stock option exercises	4,616	77
Proceeds from issuance of common stock	768	683
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(1,859)	(2,082)
Net cash used in financing activities	(37,232)	(17,488)
Effect of foreign exchange rates on cash, cash equivalents and restricted cash	(99)	4
Net increase (decrease) in cash, cash equivalents and restricted cash	10,923	(2,784)
Cash, cash equivalents and restricted cash, beginning of period	82,694	92,919
Cash, cash equivalents and restricted cash, end of period	$ 93,617	$ 90,135

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Cash Flows (Continued)
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Reconciliation to amounts within the condensed consolidated balance sheets		
Cash and cash equivalents	$ 91,475	$ 87,994
Restricted cash included in other long-term assets	2,142	2,141
Cash, cash equivalents and restricted cash at end of period	$ 93,617	$ 90,135

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note Regarding Company References and Trademarks

Unless the context otherwise requires, references to the "Company" and "Lantheus" refer to Lantheus Holdings, Inc. and its direct and indirect wholly-owned subsidiaries, references to "Holdings" refer to Lantheus Holdings, Inc. and not to any of its subsidiaries, references to "LMI" refer to Lantheus Medical Imaging, Inc., the direct subsidiary of Holdings and references to "Progenics" refer to Progenics Pharmaceuticals, Inc., a wholly-owned subsidiary of LMI. Solely for convenience, the Company refers to trademarks, service marks and trade names without the TM, SM and ® symbols. Those references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks, service marks and trade names.

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Holdings and its direct and indirect wholly-owned subsidiaries, including Progenics (as of the Closing Date, as defined below), and have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and notes required by generally accepted accounting principles in the United States of America ("U.S. GAAP") for complete financial statements. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement have been included. The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ended December 31, 2021 or any future period.

In the first quarter of fiscal year 2021, the Company completed the evaluation of its operating and reporting structure, which resulted in a change in operating segments. Please refer to Note 20, "Segment Information", for further details.

The condensed consolidated balance sheet at December 31, 2020 has been derived from the audited consolidated financial statements at that date but does not include all the information and notes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and notes thereto included in Item 8 of the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities Exchange Commission ("SEC") on February 25, 2021.

Progenics Acquisition

On June 19, 2020 (the "Closing Date"), pursuant to the Amended and Restated Agreement and Plan of Merger, dated as of February 20, 2020 (the "Merger Agreement"), by and among Holdings, Plato Merger Sub, Inc., a wholly-owned subsidiary of Holdings ("Merger Sub"), and Progenics, Holdings completed the previously announced acquisition of Progenics by means of a merger of Merger Sub with and into Progenics, with Progenics surviving such merger as a wholly-owned subsidiary of Holdings (the "Progenics Acquisition").

In accordance with the Merger Agreement, at the effective time of the Progenics Acquisition (the "Effective Time"), each share of Progenics common stock, par value $0.0013 per share, issued and outstanding immediately prior to the Effective Time (other than shares of Progenics common stock owned by Holdings, Progenics or any of their wholly-owned subsidiaries) was automatically cancelled and converted into the right to receive (i) 0.31 (the "Exchange Ratio") of a share of Holdings common stock, par value $0.01 per share, and (ii) one contingent value right (a "CVR") tied to the financial performance of PyL (18F-DCFPyL), Progenics' prostate-specific membrane antigen ("PSMA") targeted imaging agent designed to visualize prostate cancer. This agent was approved by the U.S. Food and Drug Administration ("FDA") on May 26, 2021 under the name PYLARIFY (piflufolastat F 18), and the commercial launch of this agent has begun. Each CVR will entitle its holder to receive a pro rata share of aggregate cash payments equal to 40% of U.S. net sales generated by PYLARIFY in 2022 and 2023 in excess of $100.0 million and $150.0 million, respectively. In no event will the Company's aggregate payments in respect of the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% of the total consideration the Company pays in the Progenics Acquisition (which the Company estimates could be approximately $100.0 million). No fractional shares of Holdings common stock were issued in the Progenics Acquisition, and Progenics' former stockholders have received cash in lieu of any fractional shares of Holdings common stock. As a result of the acquisition, Holdings issued 26,844,877 shares of Holdings common stock and 86,630,633 CVRs to former Progenics stockholders.

Please refer to Note 8, "Business Combinations", for further details on the acquisition.

COVID-19

The Company experienced operational and financial impacts from the COVID-19 pandemic beginning late in the first quarter of 2020 and through the date of this filing, including the impact of stay-at-home mandates and advisories, and a decline in the volume of certain procedures and treatments using the Company's products. For example, there has been a substantial reduction in pulmonary ventilation studies in which the Company's product, Xenon, is used. As a result of the COVID-19 pandemic, the Company undertook a thorough analysis of all its discretionary expenses. In the first quarter of 2020, the Company implemented certain cost reduction initiatives. For most of the second quarter of 2020, the Company reduced the Company's work week from five days to four days and reduced the pay for employees by varying amounts depending on level of seniority.

During the second quarter of 2020, Progenics also implemented certain cost reduction initiatives and paused new enrollment in the ARROW Phase 2 study of 1095, a PSMA-targeted therapeutic, in metastatic castrate-resistant prostate cancer ("mCRPC") patients to minimize the risk to subjects and healthcare providers during the pandemic. New enrollment in that study restarted in October 2020. GE Healthcare Limited ("GE Healthcare"), the Company's development and commercialization partner for flurpiridaz fluorine-18 ("F 18"), also delayed enrollment in the second Phase 3 clinical trial of flurpiridaz F 18 because of the pandemic and resumed enrollment in the third quarter of 2020.

Although some of the restrictions, including stay-at-home mandates, imposed in response to the COVID-19 pandemic have been lifted in much of the United States (the "U.S."), and there has been a rapid rollout and development of certain vaccines, the resurgence of COVID-19 infections did impact certain aspects of the Company's business during the third quarter of 2021 and the pandemic could still have a future negative impact on the Company's business, particularly if there are additional resurgences as a result of mutations or other variations to the virus that increase its communicability or its impact on certain populations, geographic regions and the healthcare system, including elective procedures and hospital access. While the impact of COVID-19 on the Company's results of operations and cash flows has been material, given continued uncertainty about the future trajectory of the pandemic, the Company remains unable to accurately predict the impact of COVID-19 on its overall 2021 operations and financial results or cash flows and whether the on-going impact of COVID-19 could lead to potential future impairments.

2. Summary of Significant Accounting Policies

Reclassifications

Certain immaterial reclassifications in the prior period condensed consolidated statements of cash flows have been reclassified to conform to the current year period financial statement presentation. Reclassifications include $0.2 million from provision for bad debt to other at September 30, 2020. The Company had a reclassification in presentation related to rebates and allowances within product revenue. Please refer to Note 3, "Revenue from Contracts with Customers" for further details.

Recent Accounting Pronouncements

Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
Accounting Standards Adopted During the Nine Months Ended September 30, 2021			
ASU 2020-06, "Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)"	This ASU provides guidance to simplify the complexity associated with accounting for convertible instruments and derivatives. For convertible instruments, the number of major separation models required were reduced. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. This ASU further amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. The ASU simplifies the diluted net income per share calculation in certain areas as well.	January 1, 2021	The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

3. Revenue from Contracts with Customers

The following table summarizes revenue by revenue source as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Major Products/Service Lines (in thousands)	**2021**	**2020**	**2021**	**2020**
Product revenue, net[1]	$ 96,678	$ 83,661	$ 277,559	$ 238,801
License and royalty revenues	5,395	4,883	18,087	6,457
Total revenues	$ 102,073	$ 88,544	$ 295,646	$ 245,258

(1) The Company's principal products include DEFINITY and TechneLite and are categorized within product revenue, net. The Company applies the same revenue recognition policies and judgments for all its principal products.

The Company classifies its revenues into three product categories: precision diagnostics, radiopharmaceutical oncology, and strategic partnerships and other. Precision diagnostics includes DEFINITY, TechneLite and other imaging diagnostic products. Radiopharmaceutical oncology consists primarily of PYLARIFY and AZEDRA. Strategic partnerships and other includes partnerships related to other products of the Company, such as RELISTOR.

Revenue by product category on a net basis is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2021**	**2020[1]**	**2021**	**2020[1]**
DEFINITY	$ 57,636	$ 50,359	$ 173,448	$ 139,989
TechneLite	22,680	21,113	69,252	62,560
Other precision diagnostics	7,563	8,585	21,289	28,782
Total precision diagnostics	87,879	80,057	263,989	231,331
Radiopharmaceutical oncology	8,890	3,323	13,203	7,474
Strategic partnerships and other	5,304	5,164	18,454	6,453
Total revenues	$ 102,073	$ 88,544	$ 295,646	$ 245,258

(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.

The Company's performance obligations are typically part of contracts that have an original expected duration of one year or less. As such, the Company is not disclosing the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied (or partially satisfied) as of the end of the reporting period.

4. Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability of fair value measurements, financial instruments are categorized based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- *Level 1* — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- *Level 2* — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).
- *Level 3* — Unobservable inputs that reflect a Company's estimates about the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The Company's financial assets and liabilities measured at fair value on a recurring basis consist of money market funds, interest rate swaps, a contingent receivable and contingent consideration liabilities. The Company invests excess cash from its operating cash accounts in overnight investments and reflects these amounts in cash and cash equivalents in the condensed consolidated balance sheets at fair value using quoted prices in active markets for identical assets. The fair value of the interest rate swaps is determined based on observable market-based inputs, including interest rate curves and reflects the contractual terms of these instruments, including the period to maturity. Please refer to Note 13, "Derivative Instruments", for further details on the interest rate swaps. The Company recorded a contingent receivable and the contingent consideration liabilities resulting from the Progenics Acquisition at fair value based on inputs that are not observable in the market. Please refer to Note 8, "Business Combinations", for further details on the acquisition.

The tables below present information about the Company's assets and liabilities measured at fair value on a recurring basis:

	September 30, 2021			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market	$ 39,141	$ 39,141	$ —	$ —
Contingent receivable	13,800	—	—	13,800
Total assets	$ 52,941	$ 39,141	$ —	$ 13,800
Liabilities:				
Interest rate swaps	$ 766	$ —	$ 766	$ —
Contingent consideration liabilities	46,800	—	—	46,800
Total liabilities	$ 47,566	$ —	$ 766	$ 46,800

	December 31, 2020			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market	$ 35,457	$ 35,457	$ —	$ —
Contingent receivable	11,300	—	—	11,300
Total assets	$ 46,757	$ 35,457	$ —	$ 11,300
Liabilities:				
Interest rate swaps	$ 1,908	$ —	$ 1,908	$ —
Contingent consideration liabilities	15,800	—	—	15,800
Total liabilities	$ 17,708	$ —	$ 1,908	$ 15,800

During the three and nine months ended September 30, 2021, there were no transfers into or out of Level 3.

As part of the Progenics Acquisition, the Company acquired the right to receive certain future milestone and royalty payments due to Progenics from CytoDyn Inc. related to a prior sale of certain intellectual property. The Company has the right to receive $5.0 million upon regulatory approval and a 5% royalty on net sales of approved products. The Company considers the contingent receivable a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value was determined based on probability adjusted discounted cash flows that included significant estimates and assumptions pertaining to regulatory events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success.

As part of the Progenics Acquisition, the Company issued CVRs and recorded the fair value as part of consideration transferred. Refer to Note 1, "Basis of Presentation" for further details on the CVRs. Additionally, the Company assumed contingent consideration liabilities related to a previous acquisition completed by Progenics in 2013 ("2013 Acquisition"). These contingent consideration liabilities include potential payments of up to $70.0 million if the Company attains certain net sales targets primarily for AZEDRA and 1095 and a $5.0 million 1095 commercialization milestone. Additionally, there is a potential payment of up to $10.0 million related to a 1404 commercialization milestone. The Company's total potential payments related to the 2013 Acquisition are approximately $85.0 million. The Company considers the contingent consideration liabilities relating to the CVRs and the 2013 Acquisition, each a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value of these was determined based on probability adjusted discounted cash flows and Monte Carlo simulation models that included significant

estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success.

Significant changes in any of the probabilities of success, the probabilities as to the periods in which milestones will be achieved, discount rates or underlying revenue forecasts would result in a significantly higher or lower fair value measurement. The Company records the contingent consideration liability at fair value with changes in estimated fair values recorded in general and administrative expenses in the condensed consolidated statements of operations. The Company can give no assurance that the actual amounts paid, if any, in connection with the contingent consideration liabilities, including the CVRs, will be consistent with any recurring fair value estimate of such contingent consideration liabilities.

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of assets and liabilities using Level 3 inputs at September 30, 2021.

	Fair Value at				Assumptions	
(in thousands)	September 30, 2021	December 31, 2020	Valuation Technique	Unobservable Input	September 30, 2021	December 31, 2020
Contingent receivable:						
Regulatory milestone	$ 3,300	$ 3,200	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2022	2021
				Probability of success	90 %	90 %
				Discount rate	18 %	24 %
Royalties	10,500	8,100	Probability adjusted discounted cash flow model			
				Probability of success	13% - 77%	13% - 77%
				Discount rate	18 %	24 %
Total	$ 13,800	$ 11,300				

	Fair Value at				Assumptions	
(in thousands)	September 30, 2021	December 31, 2020	Valuation Technique	Unobservable Input	September 30, 2021	December 31, 2020
Contingent consideration liability:						
Net sales targets - PYLARIFY (CVRs)	$ 33,200	$ 4,200	Monte Carlo simulation	Period of expected milestone achievement	2022 - 2023	2022 - 2023
				Discount rate	18 %	24 %
1095 commercialization milestone	1,900	2,200	Probability adjusted discounted cash flow model			
				Period of expected milestone achievement	2026	2026
				Probability of success	40 %	45 %
				Discount rate	0.9 %	0.5 %
Net sales targets - AZEDRA and 1095	11,700	9,400	Monte Carlo simulation			
				Probability of success	40% - 100%	40% - 100%
				Discount rate	17% - 18%	23% - 24%
Total	$ 46,800	$ 15,800				

For those financial instruments with significant Level 3 inputs, the following table summarizes the activities for the periods indicated:

(in thousands)	Financial Assets Nine Months Ended September 30,		Financial Liabilities Nine Months Ended September 30,	
	2021	2020	2021	2020
Fair value, beginning of period	$ 11,300	$ —	$ 15,800	$ —
Progenics acquisition	—	10,100	—	16,300
Changes in fair value included in net loss	2,500	100	31,000	900
Fair value, end of period	$ 13,800	$ 10,200	$ 46,800	$ 17,200

The change in fair value of the contingent financial asset and contingent financial liabilities, including the CVRs, resulted in an expense of $28.5 million for the nine months ended September 30, 2021 and was primarily due to changes in revenue forecasts, changes in market conditions, a decrease in discount rates and the passage of time.

5. Income Taxes

Historically, the Company has calculated its provision for income taxes during its interim reporting periods by applying an estimate of the annual effective tax rate for the full year to "ordinary" income or loss (pretax income or loss excluding unusual or infrequently occurring discrete events). For the three- and nine-month periods ended September 30, 2021, the Company has computed its provision for income taxes under the discrete method, which allows the Company to calculate its tax provision based upon the actual effective tax rate for the year-to-date period. We determined that since small changes in estimated "ordinary" income would result in significant changes in the estimated annual effective tax rate, the historical method would not provide a reliable estimate for the three- and nine-month periods ended September 30, 2021. The Company's income tax expense is presented below:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Income tax (benefit) expense	$ (6,422)	$ (1,076)	$ (2,967)	$ 1,425

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more-likely-than-not realizable, the Company evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. The Company assessed the need for a valuation allowance against certain state tax credit carryforwards added through the Progenics Acquisition. The Company continues to record other valuation allowances of $1.2 million against the net deferred tax assets of its U.K. subsidiary, and $2.0 million against the net deferred tax assets of its Sweden subsidiary.

In connection with the Company's acquisition of the medical imaging business from Bristol-Myers Squibb ("BMS") in 2008, the Company recorded a liability for uncertain tax positions related to the acquired business and simultaneously entered into a tax indemnification agreement with BMS under which BMS agreed to indemnify the Company for any payments made to settle those uncertain tax positions with the state taxing authorities. Accordingly, a long-term receivable is recorded to account for the expected value to the Company of future indemnification payments to be paid on behalf of the Company by BMS, net of actual tax benefits received by the Company. The tax indemnification receivable is recorded within other long-term assets.

During the third quarter of 2021, the Company entered into a settlement agreement with one state and accordingly reduced the amount of the uncertain tax positions by $5.5 million. The settlement payment to that state and the tax indemnification payment from BMS will be made in the fourth quarter of 2021. The Company continues to accrue interest on the outstanding uncertain tax positions.

In accordance with the Company's accounting policy, the change in the tax liabilities, penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within income tax expense. As these reserves change (for example, by the state tax settlement noted above), adjustments are included in income tax expense while the offsetting adjustment is included in other income. Assuming that the remaining receivable from BMS continues to be considered recoverable by the Company, there will be no effect on net income and no net cash outflows related to these liabilities.

In addition to the state tax settlement noted above, for the nine months ended September 30, 2021, the Company released $0.7 million of liabilities for uncertain tax positions, including interest and penalties of $0.5 million. This included a release of liabilities of $0.1 million, including interest and penalties of $0.4 million, due to a change in estimate with respect to the Company's indemnified uncertain tax positions arising from new information obtained during the year. The remaining release of $0.2 million of liability was due to the lapse of a statute of limitations.

On June 19, 2020, the Company completed the Progenics Acquisition in a transaction that is expected to qualify as a tax-deferred reorganization under Section 368 of the Internal Revenue Code. The transaction resulted in an ownership change of Progenics under Section 382 of the Internal Revenue Code and a limitation on the utilization of Progenics' precombination tax attributes. All of Progenics' precombination federal research and Orphan drug credits have been removed from the balance sheet, and the gross carrying value of the tax loss carryforwards reduced to their realizable value on the opening balance sheet, in accordance with the Section 382 limitation. Deferred tax liabilities arising from the purchase accounting basis step-up in identified intangibles were recorded at acquisition, resulting in an initial net overall deferred tax liability for Progenics after the application of acquisition accounting.

The Company finalized the acquisition accounting for income taxes in the first quarter of 2021 resulting in a reduction of deferred tax assets, primarily related to state research credit carryforwards and an increase to goodwill of $2.6 million.

6. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2021	December 31, 2020
Raw materials	$ 15,173	$ 16,000
Work in process	11,560	11,212
Finished goods	7,216	8,532
Total inventory	$ 33,949	$ 35,744

Inventory costs associated with products that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use of the product and future economic benefit of the asset. If future commercial use of the product is not probable, then inventory costs associated with such product are expensed during the period the costs are incurred. As of September 30, 2021, the Company had $3.2 million of such product costs included in inventories related to DEFINITY that have been manufactured through the Company's in-house manufacturing capabilities, which is awaiting regulatory approval.

7. Property, Plant and Equipment, Net

Property, plant and equipment, net, consisted of the following:

(in thousands)	September 30, 2021	December 31, 2020
Land	$ 13,450	$ 13,450
Buildings	73,285	70,381
Machinery, equipment and fixtures	82,596	77,854
Computer software	24,223	23,644
Construction in progress	8,887	11,254
	202,441	196,583
Less: accumulated depreciation and amortization	(86,000)	(76,412)
Total property, plant and equipment, net	$ 116,441	$ 120,171

Depreciation and amortization expense related to property, plant and equipment, net, was $3.6 million and $3.4 million for the three months ended September 30, 2021 and 2020, respectively, and $9.8 million and $9.1 million for the nine months ended September 30, 2021 and 2020, respectively.

The Company tests long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. During the three months ended September 30, 2021, the Company reviewed certain facts relating to an asset group that included the right-of-use ("ROU") asset associated with the lease of office space in the World Trade Center (the "WTC lease") in New York City and resulted in a change to the asset group due to the negotiation of a sublease. Please refer to Note 16, "Leases" for further details.

During the three months ended March 31, 2020, as a result of a decline in expected future cash flows and the effect of the COVID-19 pandemic related to certain other nuclear legacy manufacturing assets, the Company determined certain impairment triggers had occurred. Accordingly, the Company performed an undiscounted cash flow analysis as of March 31, 2020. Based on the undiscounted cash flow analysis, the Company determined that the manufacturing assets had net carrying values that exceeded their estimated undiscounted future cash flows. The Company then estimated the fair values of the asset group based on their discounted cash flows. The carrying value exceeded the fair value and as a result, the Company recorded a non-cash impairment of $7.3 million for the nine months ended September 30, 2020 in cost of goods sold in the condensed consolidated statements of operations.

8. Business Combinations

On June 19, 2020, the Company completed the Progenics Acquisition. The acquisition combined the commercialization, supply chain and manufacturing expertise of the Company with the currently commercialized products and research and development pipeline of Progenics. Progenics brought to the Company several commercial products and a pipeline of product candidates that further diversify the Company's commercial and clinical development portfolios.

Under the terms of the Merger Agreement, the Company acquired all the issued and outstanding shares of Progenics common stock for a purchase price of $419.0 million by means of an all-stock transaction, which includes options to purchase Holdings common stock ("Replacement Stock Options") for precombination services as well as CVRs.

The CVRs were accounted for as contingent consideration, the fair value of which was determined using a Monte Carlo simulation. Additionally, the fair value of the Replacement Stock Options was recorded as a component of consideration transferred. Finally, as a result of the Progenics Acquisition, Lantheus effectively settled an existing bridge loan with Progenics at the recorded amount (principal and accrued interest) of $10.1 million, representing the effective settlement of a preexisting relationship. This effective settlement of the bridge loan was treated as a component of consideration transferred. The Company determined that the bridge loan was at market terms and no gain or loss was recorded upon settlement.

The acquisition date fair value of the consideration transferred in the acquisition consisted of the following:

(in thousands)		Amount
Issuance of common stock	$	398,110
Fair value of replacement options		7,125
Fair value of bridge loan settled at close		10,074
Fair value of contingent considerations (CVRs)		3,700
Total consideration transferred[(1)]	$	419,009

(1) Non-cash investing and financing activities in the condensed consolidated statements of cash flows

The transaction was accounted for as a business combination which requires that assets acquired and liabilities assumed be recognized at their fair value as of the acquisition date. While the Company uses its best estimates and assumptions as part of the purchase price allocation process to value the assets acquired and liabilities assumed on the acquisition date, its estimates and assumptions are subject to refinement. Fair value estimates are based on a complex series of judgments about future events and uncertainties and rely heavily on estimates and assumptions. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations. The Company recorded a measurement period adjustment of $2.6 million related to deferred taxes for the three months ended March 31, 2021, which finalized all measurement period adjustments related to the Progenics Acquisition.

The following table summarizes the provisional amounts recognized for assets acquired and liabilities assumed as of the acquisition date, as well as measurement period adjustments made to the amounts initially recorded in June 2020. The measurement period adjustments primarily resulted from finalizing the fair values of certain intangible assets and liabilities, deferred taxes and other changes to certain tangible assets and liability accounts. Measurement period adjustments were recognized in the reporting period in which the adjustments were determined and calculated as if the accounting had been completed at the acquisition date. The related impact to net loss that would have been recognized in previous periods if the adjustments were recognized as of the acquisition date is immaterial to the consolidated financial statements.

(in thousands)	Amounts Recognized as of Acquisition Date (as previously reported)	Measurement Period Adjustments	Amounts Recognized as of Acquisition Date (as adjusted)
Cash and cash equivalents	$ 15,421	$ —	$ 15,421
Accounts receivable	5,787	—	5,787
Inventory	915	160	1,075
Other current assets	3,250	434	3,684
Property, plant and equipment	14,972	—	14,972
Identifiable intangible assets (weighted average useful life):			
Currently marketed product (15 years)	142,100	800	142,900
Licenses (11.5 years)	87,500	(1,700)	85,800
Developed technology (9 years)	3,000	(600)	2,400
IPR&D	150,900	200	151,100
Other long-term assets	37,631	—	37,631
Accounts payable	(1,616)	—	(1,616)
Accrued expenses and other liabilities	(8,207)	(80)	(8,287)
Other long-term liabilities	(30,778)	(380)	(31,158)
Long-term debt and other borrowings	(40,200)	—	(40,200)
Deferred tax liabilities	(3,717)	(2,258)	(5,975)
Goodwill	42,051	3,424	45,475
Total consideration transferred	$ 419,009	$ —	$ 419,009

Intangible assets acquired consist of currently marketed products, licenses, developed technology and in-process research and development ("IPR&D"). The fair value of the acquired intangible assets was determined based on estimated future revenues, royalty rates and discount rates, among other variables and estimates. The acquired intangible assets subject to amortization were assigned useful lives based on the expected use of the assets and the regulatory and economic environment within which they are being used and are being amortized on a straight-line basis over the respective estimated useful lives. The estimated fair values of the IPR&D assets were determined based on the present values of the expected cash flows to be generated by the respective underlying assets. The Company used a discount rate of 23.0% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

As part of the Progenics Acquisition, the Company acquired the right to receive certain future milestone and royalty payments due to Progenics, related to a prior sale of certain intellectual property. The estimated fair value of the acquired contingent receivable of $10.1 million was determined by applying a probability adjusted discounted cash flow model based on estimated future expected payments and recorded in other long-term assets.

The goodwill recognized is attributable to future technologies that are not separately identifiable that could potentially add to the currently developed and pipeline products and Progenics' assembled workforce. Future technologies did not meet the criteria for recognition separately from goodwill because they are part of the future development and growth of the business. Goodwill of $45.5 million recognized in connection with the acquisition is not deductible for tax purposes.

The Company recognized $1.6 million and $10.5 million of acquisition-related costs, including legal, accounting, compensation arrangements and other related fees that were expensed when incurred in the three and nine months ended September 30, 2020, respectively. These costs are recorded in general and administrative expenses in the condensed consolidated statements of operations.

Progenics Pro Forma Financial Information

Progenics has been included in the Company's consolidated financial statements since the acquisition date. Progenics contributed revenues of $5.9 million and $6.9 million, as well as a net loss of $12.6 million and $15.8 million to the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2020, respectively.

The following unaudited pro forma financial information presents the Company's results as if the Progenics Acquisition had occurred on January 1, 2019:

(in thousands)	Nine Months Ended September 30, 2020 Amount
Pro forma revenue	$ 256,163
Pro forma net loss	27,143

The unaudited pro forma financial information for all periods presented adjusts for the effects of material business combination items, including amortization of acquired intangible assets, transaction-related costs, adjustments to interest expense related to the assumption of long-term debt, retention and severance bonuses and the corresponding income tax effects of each. These pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the operating results of the Company that would have been achieved had the Progenics Acquisition actually taken place on January 1, 2019. In addition, these results are not intended to be a projection of future results and do not reflect events that may occur after the Progenics Acquisition, including, but not limited to, revenue enhancements, cost savings or operating synergies that the combined company may achieve as a result of the Progenics Acquisition.

9. Sale of Puerto Rico Subsidiary

During the fourth quarter of 2020, the Company entered into a stock purchase agreement (the “SPA”) with one of its existing radiopharmacy customers to sell all the stock of its Puerto Rico radiopharmacy subsidiary. The assets were classified as held for sale and the Company determined that the fair value of the net assets being sold significantly exceeded the carrying value as of December 31, 2020. The transaction was consummated on January 29, 2021.

The purchase price for the stock sale was $18.0 million in cash, which includes a holdback amount of $1.8 million to be due to the Company in January 2022; the purchase price also included a working capital adjustment. The SPA contains customary representations, warranties and covenants by each of the parties. Subject to certain limitations, the buyer will be indemnified for damages resulting from breaches or inaccuracies of the Company’s representations, warranties and covenants in the SPA.

As part of the transaction, the Company and the buyer also entered into a customary transition services agreement and a long-term supply contract under which the Company will supply the buyer with certain of the Company’s products on commercial terms and under which the buyer has agreed to certain product minimum purchase commitments.

The Company does not believe this sale of certain net assets, reported as held for sale in the international segment prior to the change in segments in the first quarter of 2021, constituted a strategic shift that would have a major effect on its operations or financial results. As a result, this transaction is not classified as discontinued operations in the Company’s accompanying condensed consolidated financial statements.

The following table summarizes the major classes of assets and liabilities sold as of January 29, 2021 (date of sale) and held for sale as of December 31, 2020:

(in thousands)	January 29, 2021	December 31, 2020
Current Assets:		
Cash and cash equivalents	$ 540	$ 941
Accounts receivable, net	1,959	2,191
Inventory	530	420
Other current assets	65	43
Total current assets	3,094	3,595
Non-Current Assets:		
Property, plant & equipment, net	780	761
Intangibles, net	96	96
Other long-term assets	774	790
Total assets held for sale	$ 4,744	$ 5,242
Current Liabilities:		
Accounts payable	$ 185	$ 224
Accrued expense and other liabilities	369	661
Total current liabilities	554	885
Non-Current Liabilities:		
Asset retirement obligations	306	302
Other long-term liabilities	588	606
Total liabilities held for sale	$ 1,448	$ 1,793

The sale resulted in a pre-tax book gain of $15.3 million, which was recorded within operating income in the condensed consolidated statements of operations for the nine months ended September 30, 2021.

10. Asset Retirement Obligations

The Company considers its legal obligation to remediate its facilities upon a decommissioning of its radioactive-related operations as an asset retirement obligation. The Company has production facilities which manufacture and process radioactive materials at its North Billerica, Massachusetts site. As of September 30, 2021, the liability is measured at the present value of the obligation expected to be incurred, of approximately $26.4 million.

The Company previously operated a production facility which manufactured and processed radioactive materials at its San Juan, Puerto Rico site. As of December 31, 2020, the liability for the San Juan, Puerto Rico site was recorded in liabilities held for sale and the sale was consummated on January 29, 2021.

The following table provides a summary of the changes in the Company's asset retirement obligations:

(in thousands)	Amount
Balance at January 1, 2021	$ 14,020
Accretion expense	1,165
Balance at September 30, 2021	$ 15,185

The Company is required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating the Company's ability to fund the decommissioning of its North Billerica, Massachusetts production facility upon closure, although the Company does not intend to close the facility. The Company has provided this financial assurance in the form of a $28.2 million surety bond.

11. Intangibles, Net

Intangibles, net, consisted of the following:

(in thousands)	Amortization Method	September 30, 2021 Cost	Accumulated Amortization	Net
Trademarks	Straight-Line	$ 13,540	$ (11,372)	$ 2,168
Customer relationships	Accelerated	96,923	(94,461)	2,462
Currently marketed products	Straight-Line	275,700	(17,275)	258,425
Licenses	Straight-Line	85,800	(9,668)	76,132
Developed technology	Straight-Line	2,400	(344)	2,056
IPR&D	N/A	15,640	—	15,640
Total		$ 490,003	$ (133,120)	$ 356,883

(in thousands)	Amortization Method	December 31, 2020 Cost	Accumulated Amortization	Net
Trademarks	Straight-Line	$ 13,540	$ (10,958)	$ 2,582
Customer relationships	Accelerated	96,865	(93,770)	3,095
Currently marketed product	Straight-Line	142,900	(5,053)	137,847
Licenses	Straight-Line	85,800	(4,008)	81,792
Developed technology	Straight-Line	2,400	(144)	2,256
IPR&D	N/A	148,440	—	148,440
Total		$ 489,945	$ (113,933)	$ 376,012

The Company recorded amortization expense for its intangible assets of $8.4 million and $4.8 million for the three months ended September 30, 2021 and 2020, respectively, and $19.1 million and $6.1 million for the nine months ended September 30, 2021 and 2020, respectively.

In May 2021, PyL (18F-DCFPyL) was approved by the FDA under the name PYLARIFY. Accordingly, the Company reclassified the associated asset of $132.8 million from IPR&D to currently marketed products and commenced amortization of the asset.

The below table summarizes the estimated aggregate amortization expense expected to be recognized on the above intangible assets:

(in thousands)	Amount
Remainder of 2021	$ 8,370
2022	33,233
2023	32,634
2024	32,563
2025	32,508
2026 and thereafter	201,935
Total	$ 341,243

12. Long-Term Debt, Net, and Other Borrowings

As of September 30, 2021, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

(in thousands)	Amount
Remainder of 2021	$ 2,500
2022	11,250
2023	15,000
2024	148,750
Total principal outstanding	177,500
Unamortized debt discount	(548)
Unamortized debt issuance costs	(473)
Finance lease liabilities	618
Total	177,097
Less: current portion	(10,356)
Total long-term debt, net and other borrowings	$ 166,741

At September 30, 2021, the Company's interest rate under the five-year secured term loan facility, which matures on June 30, 2024 (the "2019 Term Facility") was 2.1%.

On March 31, 2021, the Company voluntarily repaid in full the entire outstanding principal on the original $50.0 million loan agreement (the "Royalty-Backed Loan") with a fund managed by HealthCare Royalty Partners III, L.P. in the amount of $30.9 million, which included a prepayment amount of $0.5 million, and terminated the agreement governing the Royalty-Backed Loan. The Company recorded a gain on extinguishment of debt of $0.9 million related to the write-off of an unamortized debt premium offset by the prepayment amount.

13. Derivative Instruments

The Company uses interest rate swaps to reduce the variability in cash flows associated with a portion of the Company's forecasted interest payments on its variable rate debt. In March 2020, the Company entered into interest rate swap contracts to fix the LIBOR rate on a notional amount of $100.0 million through May 31, 2024. The average fixed LIBOR rate on the interest rate swaps is approximately 0.82%. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement without an exchange of the underlying principal amount. The interest rate swaps were designated as cash flow hedges. In accordance with hedge accounting, the interest rate swaps are recorded on the Company's condensed consolidated balance sheets at fair value, and changes in the fair value of the swap agreements are recorded to other comprehensive loss and reclassified to interest expense in the period during which the hedged transaction affected earnings or it will become probable that the forecasted transaction would not occur. At September 30, 2021, accumulated other comprehensive loss included $0.7 million of pre-tax deferred losses that are expected to be reclassified to earnings during the next 12 months.

The following table presents the location and fair value amounts of derivative instruments reported in the condensed consolidated balance sheets:

(in thousands)		September 30, 2021	December 31, 2020
Derivatives type	**Classification**		
Liabilities:			
Interest rate swap	Accrued expenses and other liabilities	$ 766	$ 1,908

14. Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss, net of tax of $0.2 million and $0.5 million for the nine months ended September 30, 2021 and 2020, respectively, consisted of the following:

(in thousands)	Foreign currency translation	Unrealized loss on cash flow hedges	Accumulated other comprehensive loss
Balance at January 1, 2021	$ (630)	$ (1,418)	$ (2,048)
Other comprehensive income before reclassifications	55	312	367
Amounts reclassified to earnings	—	539	539
Balance at September 30, 2021	$ (575)	$ (567)	$ (1,142)
Balance at January 1, 2020	$ (960)	$ —	$ (960)
Other comprehensive loss before reclassifications	(9)	(1,784)	(1,793)
Amounts reclassified to earnings	—	243	243
Balance at September 30, 2020	$ (969)	$ (1,541)	$ (2,510)

15. Stock-Based Compensation

The following table presents stock-based compensation expense recognized in the Company's accompanying condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2021	2020	2021	2020
Cost of goods sold	$ 144	$ 864	$ 1,672	$ 2,127
Sales and marketing	684	621	1,726	1,268
General and administrative	2,330	1,926	6,641	5,735
Research and development	709	581	1,733	1,322
Total stock-based compensation expense	$ 3,867	$ 3,992	$ 11,772	$ 10,452

16. Leases

Operating and finance lease assets and liabilities are as follows:

(in thousands)	Classification	September 30, 2021	December 31, 2020
Assets			
Operating	Other long-term assets	$ 8,287	$ 18,441
Finance	Property, plant and equipment, net	508	525
Total leased assets		$ 8,795	$ 18,966
Liabilities			
Current			
Operating	Accrued expenses and other liabilities	$ 1,397	$ 1,164
Finance	Current portion of long-term debt and other borrowings	356	249
Noncurrent			
Operating	Other long-term liabilities	16,391	17,501
Finance	Long-term debt, net and other borrowings	262	246
Total leased liabilities		$ 18,406	$ 19,160

The Company leases office space in the World Trade Center in New York City. In the third quarter of 2021, the Company negotiated a sublease agreement with an unrelated third party that was signed on October 11, 2021 (the "Sublease") and has a term of nine years, which represents the remaining term of the WTC lease. Both the WTC lease and the Sublease are classified by the Company as operating leases. As a result of the negotiations of the Sublease, the Company determined that an impairment triggering event had occurred. Accordingly, the Company performed an undiscounted cash flow analysis related to the asset group as of September 30, 2021. Based on the undiscounted cash flow analysis, the Company determined that the asset group, including the ROU asset, had net carrying values that exceeded their estimated undiscounted future cash flows. The Company then estimated the fair value of the asset group based on its discounted cash flows. The carrying value exceeded the fair value and, as a result, the Company recorded a non-cash impairment of $9.5 million for the three and nine months ended September 30, 2021 in general and administrative expenses in the condensed consolidated statements of operations.

17. Net Loss Per Common Share

A summary of net loss per common share is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2021**	**2020**	**2021**	**2020**
Net loss	$ (13,415)	$ (6,386)	$ (31,064)	$ (10,061)
Basic weighted-average common shares outstanding	67,623	66,820	67,409	49,858
Basic and diluted loss per common share	$ (0.20)	$ (0.10)	$ (0.46)	$ (0.20)
Antidilutive securities excluded from diluted net income per common share	3,051	2,588	3,051	1,657

18. Other Loss (Income)

Other loss (income) consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Foreign currency losses (gains)	$ 127	$ (33)	$ 156	$ 187
Tax indemnification loss (income), net	3,823	(555)	3,092	(1,664)
Interest income	(11)	(7)	(39)	(221)
Other	1	(1)	—	(4)
Total other loss (income)	$ 3,940	$ (596)	$ 3,209	$ (1,702)

19. Commitments and Contingencies

Legal Proceedings

From time to time, the Company is a party to various legal proceedings arising in the ordinary course of business. In addition, the Company has in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities, which expose it to greater risks associated with litigation, regulatory or other proceedings, as a result of which the Company could be required to pay significant fines or penalties. The costs and outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to the Company and could have a material adverse effect on the Company's results of operations or financial condition. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against the Company, could materially and adversely affect its financial condition or results of operations. If a matter is both probable to result in material liability and the amount of loss can be reasonably estimated, the Company estimates and discloses the possible material loss or range of loss. If such loss is not probable or cannot be reasonably estimated, a liability is not recorded in its condensed consolidated financial statements.

As of September 30, 2021, the Company had the following material ongoing litigation in which the Company was a party:

RELISTOR European Opposition Proceedings

In October 2015, Progenics received notices of opposition to three European patents relating to methylnaltrexone: EP1615646, EP2368553 and EP2368554. Notices of opposition were filed separately at the European Patent Office (the "EPO") by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH. Between May 11, 2017 and July 4, 2017, the Opposition Division of the EPO (the "Opposition Division") provided notice that the three European patents would be revoked. Each of these matters was appealed to the Appeal Board of the EPO. On November 13, 2020, Progenics withdrew the appeal for EP2368553 and EP2368554. Notices of termination of the proceedings with revocation of the patent were issued on November 23, 2020 for both patents.

Progenics continued its appeal for the revocation of the third patent, EP1615646. Oral proceedings for EP1615646 were held at the Appeal Board of the EPO on September 22, 2020. The revocation decision under appeal was set aside and the case was remitted to the Opposition Division for further prosecution. An oral hearing was held before the Opposition Division on September 27, 2021. The parties are awaiting the final written decision of the Opposition Division. The final written decision of the Opposition Division is appealable to the Appeal Board of the EPO by either party. Because the outcome of opposition and appeal proceedings at the EPO is uncertain, the Company cannot predict how or when this matter will ultimately be resolved.

German PSMA-617 Litigation

On November 8, 2018, Molecular Insight Pharmaceuticals, Inc., a subsidiary of Progenics ("MIP"), filed a complaint against the University of Heidelberg (the "University") in the District Court in Mannheim, Germany (the "German District Court"). In this Complaint, MIP claimed that the discovery and development of PSMA-617 was related to work performed under a research collaboration sponsored by MIP. MIP alleged that the University breached certain contracts with MIP and that MIP is the co-owner of inventions embodied in certain worldwide patent filings related to PSMA-617 that were filed by the University. On February 27, 2019, Endocyte, Inc., a wholly owned subsidiary of Novartis AG, filed a motion to intervene in the German litigation. Endocyte is the exclusive licensee of the patent rights that are the subject of the German proceedings.

On November 27, 2018, MIP requested that the EPO stay the examination of a certain European Patent and related Divisional Applications, pending a decision from the German District Court on MIP's Complaint. On December 10, 2018, the EPO granted MIP's request and stayed the examination of the patent and patent applications effective November 27, 2018. MIP filed a Confirmation of Ownership with the United States Patent and Trademark Office ("USPTO") in corresponding U.S. patent applications (U.S. Serial Nos. 15/131,118; 15/805,900; 16/038,729, 16/114,988, 16/510,495, 16/551,198, and 17/110,558). MIP's filing with the USPTO takes the position that, in light of the collaboration and contracts between MIP and the University, MIP is the co-owner of these pending U.S. patent applications (U.S. Serial Nos. 16/510,495, 16/551,198). On March 6, 2020, MIP filed with the USPTO a notice stating that the Power of Attorney in certain pending U.S. patent applications was signed by less than all applicants or owners of the applications.

On February 27, 2019, the German District Court set €0.4 million as the amount MIP must deposit with the German District Court as security in the event of an unfavorable final decision on the merits of the dispute. The German District Court held the first oral hearing in the case on August 6, 2019. The German District Court considered procedural matters and granted the parties the right to make further submissions. A further oral hearing occurred July 23, 2020, during which the German District Court heard live testimony from several witnesses, testifying on behalf of the defendants. On August 24, 2020, the German District Court issued its decision dismissing MIP's claims, stating that MIP failed to discharge its burden of proof in the matter.

MIP filed a Notice of Appeal of the German District Court's decision on September 24, 2020 and filed its appeal brief on November 26, 2020. The University and Endocyte each filed oppositions to MIP's Notice of Appeal on March 12, 2021. An oral hearing for the appeal is scheduled for February 9, 2022, at the Higher Regional Court Karlsruhe. MIP is also considering its legal and procedural alternatives against the defendants in other jurisdictions and proceedings. If MIP is not successful in its appeal, it will be responsible for the German court fees and fees and disbursements of defendant's and intervenor's counsel, both at first instance and on appeal. Most of such fees and disbursements at first instance are covered by a cash security deposited with the German District Court. Because the outcome of litigation is uncertain, the Company cannot predict how or when this matter will ultimately be resolved.

Petition for Post-Grant Review

On February 4, 2021, Advanced Accelerator Applications USA, Inc. ("AAA") filed a petition for post-grant review of U.S. Patent No. 10,640,461 (the "'461 patent") with the Patent Trial and Appeal Board ("PTAB") of the USPTO. The '461 patent is owned by MIP. In the petition, AAA challenges the patentability of claims 1, 45, and 47 of the '461 patent under 35 U.S.C. §§ 112 and 102(a)(1). The PTAB instituted Post-Grant Review ("PGR") proceedings on July 29, 2021. MIP's written response to the PTAB is due by December 9, 2021. The PTAB generally issues a final written decision on the validity of the challenged claims within one year of institution of the PGR proceedings. The outcome of PGR proceedings is uncertain and the Company cannot predict whether the challenged claims 1, 45 and 47 of the '461 patent will be deemed to be valid or invalid.

20. Segment Information

In the first quarter of fiscal year 2021, the Company completed the evaluation of its operating and reporting structure, including the impact on the Company's business of the acquisition of Progenics described in Notes 1 and 8, and the sale of the Puerto Rico subsidiary in the first quarter, which resulted in a change in operating and reportable segments. The Company now operates as one business segment: the development, manufacture and sale of innovative diagnostic and therapeutic agents and products that assist clinicians in the diagnosis and treatment of heart disease, cancer and other diseases. This conclusion reflects the Company's focus on the performance of the business on a consolidated worldwide basis. The results of this operating segment are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive Officer. The Company's chief operating decision maker does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results.

21. Subsequent Events

On October 11, 2021, the Company signed a sublease for certain office space. See Note 16, "Leases", for further details.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

Some of the statements contained in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and can generally be identified by words such as "anticipates," "believes," "can," "could," "estimates," "expects," "hopes," "intends," "launch," "may," "pipeline," "plans," "predicts," "seeks," "should," "target," "will," "would" and similar expressions, or by express or implied discussions regarding potential marketing approvals or new indications for the collaborations, products candidates or approved products described in this Quarterly Report on Form 10-Q, or regarding potential future revenues from such collaborations, product candidates and products. Examples of forward-looking statements include statements we make relating to our outlook and expectations including, without limitation, in connection with: (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 FDA 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 ("Mo-99") supply; (v) our products manufactured at Jubilant HollisterStier ("JHS") and our modified formulation of DEFINITY ("DEFINITY RT") to be commercially manufactured at Samsung Biologics ("SBL"), 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, otherwise known 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; and (xi) our ability to develop highly contextualized assessments of disease burden using artificial intelligence ("AI"). Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, such statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. These statements are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this Quarterly Report on Form 10-Q may not in fact occur. We caution you, therefore, against relying on any of these forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake 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.

Available Information

Our global Internet site is www.lantheus.com. We routinely make available important information, including copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after those reports are electronically filed with, or furnished to, the SEC, free of charge on our website at investor.lantheus.com. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of this Quarterly Report on Form 10-Q, and any website references are not intended to be made through active hyperlinks.

Our reports filed with, or furnished to, the SEC are also available on the SEC's website at www.sec.gov, and for Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, in an iXBRL (Inline Extensible Business Reporting Language) format. iXBRL is an electronic coding language used to create interactive financial statement data over the Internet. The information on our website is neither part of nor incorporated by reference into this Quarterly Report on Form 10-Q.

The following discussion and analysis of our financial condition and results of operations should be read together with the condensed consolidated financial statements and the related notes included in Item 1 of this Quarterly Report on Form 10-Q as well as the other factors described in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q.

Overview

Our Business

We are 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. Clinicians use our agents and products in echocardiography, nuclear imaging, and oncologic therapeutics. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving better patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

Our commercial products are used by cardiologists, nuclear medicine physicians, radiologists, oncologists, urologists, internal medicine physicians, technologists and sonographers working in a variety of clinical settings. We sell our products to radiopharmacies, integrated delivery networks, hospitals, clinics and group practices.

We produce and market our agents and products throughout the U.S., selling primarily to radiopharmacies, integrated delivery networks, hospitals, clinics and group practices. We sell our agents and products outside the U.S. through a combination of direct distribution in Canada and third-party distribution relationships in Europe, Canada, Australia, Asia-Pacific and Latin America.

In the first quarter of fiscal year 2021, we completed the evaluation of our operating and reporting structure, including the impact on our business of the acquisition of Progenics, and the sale of our Puerto Rico subsidiary in the first quarter, which resulted in a change in our operating segments to one reportable business segment.

PYLARIFY Approval and Commercial Launch

On May 27, 2021, we announced that the FDA had approved PYLARIFY, an F 18-labeled positron emission tomography (“PET”) imaging agent targeting prostate-specific membrane antigen (“PSMA”). PYLARIFY enables the visualization of primary prostate tumors as well as bone and soft tissue metastases, with potential high clinical utility in the detection of recurrent and/or metastatic prostate cancer. The approval of PYLARIFY was based on data from two Company-sponsored pivotal studies (“OSPREY” and “CONDOR”) designed to establish the safety and diagnostic performance of PYLARIFY across the prostate cancer disease continuum. Results from OSPREY (Cohort A) demonstrated improvement in specificity and positive predictive value of PYLARIFY PET imaging over conventional imaging in men at risk for metastatic prostate cancer prior to initial definitive therapy. CONDOR studied men with biochemical recurrent prostate cancer. In patients with biochemical recurrent prostate cancer and non-informative baseline imaging, PYLARIFY demonstrated high correct localization and detection rates, including in patients with low prostate-specific antigen (“PSA”) blood level values (median PSA 0.8 ng/mL).

Upon approval, PYLARIFY was immediately available in parts of the U.S., such as the mid-Atlantic and the South. Since its approval, PYLARIFY availability has expanded into additional regions, including six of the largest metropolitan areas in the U.S. - New York, Los Angeles/San Diego, Chicago, Dallas, Houston, and Washington, D.C. – as well as select locations in the Southeast, the Midwest, the Southwest, the Northeast and the Northwest. We expect PYLARIFY availability to continue to expand across the U.S. over the remainder of the year, with broad nationwide availability anticipated by year end.

The commercial launch of PYLARIFY is complex and expensive. During 2021, we hired additional employees to assist us with the commercialization of PYLARIFY, including in sales, marketing, reimbursement, quality and medical affairs. To manufacture PYLARIFY, we have assembled and are qualifying a nationwide network of PMFs with radioisotope-producing cyclotrons that make fluorine-18, which has a 110-minute half-life, so PYLARIFY is manufactured and distributed rapidly to end-users. After being made on a cyclotron at a PMF, the F 18 is then combined with certain chemical ingredients in specially designed chemistry synthesis boxes to manufacture PYLARIFY, which is then transferred to a radiopharmacist who prepares and dispenses patient-specific doses of the final product. Because each of the PMFs manufacturing these products is deemed by the FDA to be a separate manufacturing site, each has to be approved by the FDA. Although we are able to provide PYLARIFY in the regions listed above, we can give no assurance that the FDA will continue to approve PMFs in accordance with our planned roll-out schedule. If FDA approval of manufacturing sites is delayed, our future business, results of operations, financial condition and cash flows could be adversely affected.

In addition, obtaining adequate reimbursement for PYLARIFY will be critical, including not only coverage from Medicare, Medicaid and other government payors, as well as private payors, but also appropriate payment levels, which adequately cover the

manufacturing and distribution costs associated with an F 18-based agent. We can give no assurance that pass-through status will be granted or that other adequate reimbursement can be secured to allow PYLARIFY to become successfully commercialized.

Key Factors Affecting Our Results

Our 2021 financial performance will reflect full year results of the Progenics business, whereas the prior year only incorporated results since the Closing Date. We also expect that the approval of PYLARIFY in May 2021 and subsequent launch will result in increased revenues.

Our business and financial performance have been, and continue to be, affected by the following:

COVID-19 Pandemic

The global COVID-19 pandemic has had, and may continue to have, a material impact on our business. Towards the end of the first quarter of 2020 we began to experience, and through the date of this filing we are continuing to experience, impacts to our business and operations related to the COVID-19 pandemic, including the impact of stay-at-home mandates and advisories, and a decline in the volume of certain procedures and treatments using our products.

For example, there has been a substantial reduction in pulmonary ventilation studies in which our product, Xenon, is used because of institutional concerns and professional society guidelines relating to the possible spread of COVID-19 to technicians and other patients, given that Xenon is both inhaled and exhaled by the patient. As a result, Xenon sales have decreased significantly. In March 2021, the Society of Nuclear Medicine and Medical Imaging (“SNMMI”), updated its guidance regarding in-hospital respiratory inhalation procedures administered (or performed) during the pandemic, modifying its previous position. Based on advances in testing and procedural protocols since the onset of the pandemic as well as increasing vaccination rates, SNMMI now allows that under appropriate conditions for safe administration, pulmonary ventilation studies can be performed where necessary to reach a definitive diagnosis for a patient. Notwithstanding this change in March 2021, our Xenon sales through the third quarter of 2021 continued to be at reduced levels, and we expect these reduced levels to continue for at least as long as COVID-19 precautions remain in place. We can give no assurance that Xenon sales will return to historic levels.

As a result of the COVID-19 pandemic, we undertook a thorough analysis of all our discretionary expenses. In the first quarter of 2020, we implemented certain cost reduction initiatives. For most of the second quarter of 2020, we reduced our work week from five days to four days and reduced the pay for our personnel by varying amounts, depending on level of seniority.

During the second quarter of 2020, Progenics also implemented certain cost reduction initiatives, and new enrollment in the ARROW Phase 2 study of 1095 in mCRPC patients was paused to minimize the risk to subjects and healthcare providers during the pandemic. New enrollment in that study restarted in October 2020.

GE Healthcare, our development and commercialization partner for flurpiridaz F 18, also delayed enrollment in the second Phase 3 clinical trial because of the pandemic and resumed enrollment in the third quarter of 2020.

Although some of the restrictions, including stay-at-home mandates, imposed in response to the COVID-19 pandemic have been lifted in much of the United States, and there has been a rapid rollout and development of certain vaccines, the resurgence of COVID-19 infections did impact certain aspects of our business during the third quarter of 2021 and the pandemic could still have a future negative impact on our business, particularly if there are additional resurgences as a result of mutations or other variations to the virus that increase its communicability or its impact on certain populations, geographic regions and the healthcare system, including elective procedures and hospital access.

While we are currently unable to estimate the impact of COVID-19 on our overall 2021 operations and financial results, we ended the third quarter of 2021 with $91.5 million of cash and cash equivalents. With our available liquidity and prudent expense management, we currently believe that we have sufficient financial resources to operate our business, support our customers, launch PYLARIFY as a new commercial product, and support the continued development of our product candidate pipeline, although we can give no assurances that we will have sufficient liquidity for all of these items, as the future trajectory of the pandemic is unknown and may affect our liquidity.

Anticipated Continued Growth of DEFINITY and Expansion of Our Ultrasound Microbubble Franchise

We believe the market opportunity for our ultrasound microbubble enhancing agent, DEFINITY, continues to be significant. DEFINITY has been our fastest growing and highest margin commercial product. We anticipate DEFINITY sales will continue to grow in the future. As we continue to educate the physician and healthcare provider community about the benefits and risks of DEFINITY, we believe we will be able to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. In a U.S. market with three echocardiography ultrasound enhancing agents approved by the FDA, we estimate that DEFINITY had over 80% of the market as of December 31, 2020.

As we continue to pursue expanding our microbubble franchise, our activities include:

- Patents - We continue to actively pursue additional patents in connection with DEFINITY and DEFINITY RT, both in the U.S. and internationally. In the U.S. for DEFINITY, we now own a total of four Orange Book-listed method of use patents, one of which expires in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2023 and 2037. In the U.S. for DEFINITY RT, we now own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY patent protection and regulatory exclusivity have generally expired, we are currently prosecuting additional DEFINITY and DEFINITY RT patents to obtain similar patent protection as in the U.S. The Orange Book-listed patents include a patent on the use of VIALMIX RFID which expires in 2037; additional VIALMIX RFID patent applications have been submitted in major markets throughout the world.

  Hatch-Waxman Act - Even though our longest duration Orange Book-listed DEFINITY patent extends until March 2037, because our Orange Book-listed composition of matter patent expired in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve Abbreviated New Drug Applications ("ANDAs") for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent or that an Orange Book-listed patent is invalid. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give a notice to the innovator (a "Notice") that the ANDA applicant certifies that its generic candidate will not infringe the innovator's Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving that Notice, and FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months (measured from the date on which a Notice is received) while the patent dispute between the innovator and the ANDA applicant is resolved in court. The 30-month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

  As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30-month stay, then the ANDA applicant would be precluded from commercializing a generic version of DEFINITY prior to the expiration of that 30-month stay period and, potentially, thereafter, depending on how the patent dispute is resolved. Solely by way of example and not based on any knowledge we currently have, if we received a Notice from an ANDA applicant in November 2021 and the full 30-month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least May 2024. If we received a Notice some number of months in the future and the full 30-month stay was obtained, the commercialization date would roll forward in the future by the same calculation.

- *DEFINITY RT* - In November 2020, the FDA approved our supplemental new drug application ("sNDA") for DEFINITY RT. DEFINITY RT is a modified formulation of DEFINITY that allows both storage and shipment at room temperature (DEFINITY's previously approved formulation requires refrigerated storage). The modified formulation provides clinicians an additional choice and allows for greater utility of this formulation in broader clinical settings. We believe DEFINITY RT will become commercially available in the fourth quarter of 2021, although that timing cannot be assured. Given its physical characteristics, we believe DEFINITY RT is also well-suited for inclusion in kits requiring microbubbles for other indications and applications (including in kits developed by third parties of the type described in the paragraph entitled *Additional Clinical Applications* below).

- *Vialmix RFID* – In August 2020, we announced the FDA approved our sNDA for our next-generation activation device designed specifically for both DEFINITY and DEFINITY RT. The activation rate and time are controlled by VIALMIX RFID through the use of radio-frequency identification technology ("RFID") to ensure reproducible activation of DEFINITY and DEFINITY RT. The RFID tag, which is affixed to the vial label, enables the DEFINITY or DEFINITY RT vial to be appropriately activated when utilized with the VIALMIX RFID activation device. We believe VIALMIX RFID will become available in the fourth quarter of 2021, although that timing cannot be assured.

- *Additional Clinical Applications* - As we continue to look for other opportunities to expand our microbubble franchise, we are evaluating new indications and clinical applications beyond echocardiography and ultrasound enhancing agent imaging generally. Prior to 2021, we entered into the following collaborations: (i) Cerevast Medical, Inc. ("Cerevast") in which our microbubble will be used in connection with Cerevast's ocular ultrasound device to improve blood flow in occluded retinal veins in the eye; (ii) CarThera SAS ("CarThera") for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma; and (iii) Insightec Ltd. ("Insightec") which will use our microbubbles in connection with the development of Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions. In April 2021, we announced a strategic collaboration with Allegheny Health Network ("AHN") which will use our microbubbles in combination with AHN's ultrasound-assisted non-viral gene transfer technology for the development of a proposed treatment

of xerostomia. Xerostomia is a lack of saliva production leading to dry mouth and has a variety of causes, including radiotherapy and chemotherapy, the chronic use of drugs and rheumatic and dysmetabolic diseases.

- *In-House Manufacturing* - We have completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility for DEFINITY and, potentially, other sterile vial products. We believe this investment will allow us to better control DEFINITY manufacturing and inventory, reduce our costs in a potentially more price competitive environment, and provide us with supply chain redundancy. We have filed our sNDA with the FDA and currently expect to have DEFINITY manufactured at this facility commercially available in early 2022, although the approval of our sNDA and that timing cannot be assured.
- *DEFINITY in China* - In March 2020, in connection with our Chinese development and distribution arrangement with Double-Crane Pharmaceutical Company ("Double-Crane"), we filed an Import Drug License application with the National Medical Products Administration, or the NMPA, for the use of DEFINITY for the echocardiography indication. We believe this is an important milestone in our efforts to commercialize DEFINITY in China. Double-Crane is also in the process of analyzing the clinical results relating to the liver and kidney indications and will also work with us to prepare an Import Drug License application for those indications.

Global Mo-99 Supply

We currently have Mo-99 supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2022, with auto-renewal provisions subject to notice of non-renewal, and with NTP Radioisotopes ("NTP") and the Australian Nuclear Science and Technology Organisation ("ANSTO"), running through December 31, 2021, and for which we are currently negotiating an extension. We also have a Xenon supply agreement with IRE which runs through June 30, 2022, and which is subject to further extension.

Although we have a globally diverse Mo-99 supply with IRE in Belgium, NTP in South Africa, and ANSTO in Australia, we still face supplier and logistical challenges in our Mo-99 supply chain. The NTP processing facility had periodic outages in 2017, 2018 and 2019. When NTP was not producing, we relied on Mo-99 supply from both IRE and ANSTO to limit the impact of the NTP outages. In 2019 and 2020, ANSTO experienced multiple facility issues that resulted in ANSTO outages and volume limitations, during which time we relied on IRE and NTP to limit the impact of those outages and limitations. Because of the COVID-19 pandemic, we experienced challenges receiving regularly scheduled orders of Mo-99 from our global suppliers, particularly in the second quarter of 2020. We continue to manage these various supply chain challenges, but depending on reactor and processor schedules and operations, at times we have not been able to fill some or all of the demand for our TechneLite generators on certain manufacturing days. A prolonged disruption of service from one of our three Mo-99 processing sites or one of their main Mo-99-producing reactors could have a substantial negative effect on our business, results of operations, financial condition and cash flows.

We are also pursuing additional sources of Mo-99 from potential new producers to further augment our current supply. In November 2014, we entered into a strategic arrangement with SHINE Medical Technologies LLC ("SHINE") for the future supply of Mo-99. Under the terms of the supply agreement, SHINE will provide Mo-99 produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE's facility becomes operational and receives all necessary regulatory approvals, which SHINE now estimates will occur in late 2022. However, we cannot assure you that SHINE or any other possible additional sources of Mo-99 will result in commercial quantities of Mo-99 for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Mo-99 to meet our needs.

Inventory Supply

We obtain a substantial portion of our imaging agents from a third-party supplier. JHS is currently our sole source manufacturer of DEFINITY, NEUROLITE, Cardiolite and evacuation vials, the latter being an ancillary component for our TechneLite generators. We are currently seeking approval from certain foreign regulatory authorities for JHS to manufacture certain of our products. Until we receive these approvals, we will face continued limitations on where we can sell those products outside of the U.S. In addition to JHS, we rely on SBL as our sole source manufacturer of DEFINITY RT. Our manufacturing agreement with JHS relating to DEFINITY expires in February 2022, and our manufacturing agreements relating to NEUROLITE and Cardiolite expire in December 2023, in each case, with auto-renewal provisions subject to notice of non-renewal. On July 27, 2021, we received a letter from JHS that it was providing notice of non-renewal of our manufacturing agreement relating to DEFINITY, but that JHS remained interested in negotiating a new agreement. We are actively negotiating a new manufacturing agreement with JHS for DEFINITY, although there is no assurance that we will be able to reach an agreement on mutually acceptable terms or at all. In the event we are not able to enter into an agreement on mutually acceptable terms or at all, we expect that we would exercise our right under our current agreement with JHS to request a terminal supply of DEFINITY in an amount sufficient to meet our supply needs for DEFINITY until our in-house manufacturing facility is operational and producing enough DEFINITY to meet our supply needs, although there is no assurance that there would be no disruption.

We have completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility for DEFINITY and, potentially, other sterile vial products, which will also allow us to optimize our costs and reduce our supply chain risk, including in the event we cannot enter into a new agreement with JHS for DEFINITY as noted above. We have filed our sNDA with the FDA and currently expect to have DEFINITY manufactured at this facility commercially available in early 2022, although the approval of our sNDA and that timing cannot be assured.

Radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. These products cannot be kept in inventory because of their limited shelf lives and are subject to just-in-time manufacturing, processing and distribution, which takes place at our facilities in North Billerica, Massachusetts and Somerset, New Jersey.

Integration of the Progenics Acquisition

On June 19, 2020, we completed the Progenics Acquisition. Progenics' portfolio of products and product candidates included, among other things, therapeutic agents designed to target cancer (AZEDRA, 1095 and PSMA TTC), diagnostic imaging agents designed to target PSMA for prostate cancer (PYLARIFY and 1404), RELISTOR for opioid-induced constipation, AI imaging technologies and leronlimab being developed for HIV infection. Progenics' revenue was generated from two principal sources: first, royalties and development and commercial milestones from strategic partnerships, including royalties from Bausch Health Companies, Inc. ("Bausch") from sales of RELISTOR; and second, AZEDRA sales.

The ultimate success of the Progenics Acquisition will depend on our ability to successfully combine the business of Progenics with our own and realize the anticipated benefits, including synergies, cost savings, innovation and operational efficiencies and revenue growth from the acquisition.

Our combined business is now larger and significantly more complex than our business was immediately prior to the consummation of the Progenics Acquisition. Our ability to successfully manage this combined business will depend upon our ability to continue to integrate and manage the combined business with its increased scale and scope, and increased costs and complexity. In addition, the CVRs issued as partial consideration for the Progenics Acquisition create additional operational obligations and accounting complexity. See Part II, Item 1A. "Risk Factors - The CVRs we issued as part of the Progenics Acquisition may result in substantial future payments and could divert the attention of our management; in addition, the actual payments made in connection with the CVRs, if any, may not be consistent with the estimated fair value of the CVRs that we are required to prepare for accounting purposes." We can give no assurance that the actual amounts paid, if any, in connection with the CVRs will be consistent with any recurring fair value estimate of such CVRs.

Research and Development Expenses

To remain a leader in the marketplace, we have historically made substantial investments in new product development, including, among other things, our flurpiridaz F 18 clinical development program, the expenses of which are now being borne by GE Healthcare. The Progenics Acquisition resulted in additional and substantial clinical development expense. The PYLARIFY NDA filed with the FDA on September 29, 2020, was approved by the FDA in May 2021. For 1095, the ARROW Phase 2 study in mCRPC patients had been paused to minimize risk to subjects and healthcare providers during the pandemic, and new enrollment in that study restarted in October 2020. In the fourth quarter of 2021, we completed an interim analysis of the ARROW Phase 2 study. The Independent Data Monitoring Committee recommended the study continue without modifications.

We also are planning additional clinical development work for AZEDRA in two new potential therapeutic indications – neuroblastoma and gastroenteropancreatic neuroendocrine tumors – and LMI 1195 as a diagnostic agent for the management of neuroblastoma. In addition, the Company has developed aPROMISE, our artificial intelligence-based, deep learning-enabled, medical device software, which we also refer to as PYLARIFY AI, and which is further described below under the heading "Additional Initiatives". Our investments in these additional clinical activities will increase our operating expenses and impact our results of operations and cash flow, and we can give no assurances as to whether any of these clinical development candidates will be approved.

Additional Initiatives

In addition to integrating the new assets and programs resulting from the Progenics Acquisition, we continue to seek ways to further expand our portfolio of products and product candidates and how best to optimize the value of our current assets, evaluating a number of different opportunities to collaborate with others or to acquire or in-license additional products, product candidates, businesses and technologies to drive our future growth. Consistent with the Progenics Acquisition, we are particularly interested in expanding our presence in oncology, in both radiotherapeutics and diagnostics.

- In May 2019, we commenced an initiative to build out our Pharma Services capabilities, which resides in our strategic partnerships and other revenue product category, by entering into a strategic collaboration and license agreement with NanoMab, a privately-held biopharmaceutical company focusing on the development of next generation radiopharmaceuticals for cancer precision medicine. We believe this collaboration will provide the first broadly-available

PD-L1 imaging biomarker research tool to pharmaceutical companies and academic centers conducting clinical trials on immuno-oncology treatments, including combination therapies.

- In March 2021, we acquired from Ratio Therapeutics LLC ("Ratio") (previously Noria Therapeutics, Inc.) exclusive, worldwide rights to NTI-1309, an innovative imaging biomarker that targets fibroblast activation protein ("FAP"), an emerging target with broad potential imaging applicability and use in oncology. Under the terms of this agreement, Ratio will drive the early clinical development of NTI-1309. We are integrating NTI-1309 into our portfolio of imaging biomarkers as part of our Pharma Services offering. Upon further clinical development, we will assess options to bring NTI-1309 to market as a diagnostic or potentially a therapeutic agent.
- We have also expanded our Pharma Services offering to include piflufolastat F 18 for pharmaceutical companies developing PSMA-targeted therapies and have entered into clinical supply agreements with each of Regeneron, Bayer and POINT BioPharma for use of piflufolastat F 18 in prostate cancer drug development programs. In September 2021, we entered into a development and commercialization collaboration with RefleXion Medical, Inc. to evaluate the use of piflufolastat F 18 to enable real-time therapeutic guidance of biology-guided radiotherapy in prostate cancer using the RefleXion X1™ platform.
- Our subsidiary, EXINI Diagnostics AB ("EXINI"), has developed PYLARIFY AI, which is designed to allow healthcare professionals and researchers to perform quantitative assessments of PSMA PET/CT in oncology. Clinicians will have the option to utilize PYLARIFY AI with PYLARIFY to increase the efficiency and reproducibility of the PSMA PET/CT assessments. Earlier this year, we announced that EXINI was granted 510(k) clearance by the FDA for PYLARIFY AI in the U.S. and that EXINI received CE Mark clearance for PYLARIFY AI in Europe.

We can give no assurance as to when or if any of these Pharma Services collaborations and other new initiatives will be successful or accretive to earnings.

In addition, as described above, we continue to expand our microbubble franchise. See "Anticipated Continued Growth of DEFINITY and Expansion of Our Ultrasound Microbubble Franchise–New Clinical Applications" for further details.

Results of Operations

The following is a summary of our consolidated results of operations:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	**2021**	**2020**	**Change $**	**Change %**	**2021**	**2020**	**Change $**	**Change %**
Revenues	$ 102,073	$ 88,544	$ 13,529	15.3 %	$ 295,646	$ 245,258	$ 50,388	20.5 %
Cost of goods sold	59,404	52,284	7,120	13.6 %	165,859	145,148	20,711	14.3 %
Gross profit	42,669	36,260	6,409	17.7 %	129,787	100,110	29,677	29.6 %
Operating expenses								
Sales and marketing	17,195	11,609	5,586	48.1 %	48,999	28,044	20,955	74.7 %
General and administrative	28,550	18,217	10,333	56.7 %	87,865	55,586	32,279	58.1 %
Research and development	11,252	11,684	(432)	(3.7)%	33,673	20,150	13,523	67.1 %
Total operating expenses	56,997	41,510	15,487	37.3 %	170,537	103,780	66,757	64.3 %
Gain on sale of assets	—	—	—	N/A	15,263	—	15,263	N/A
Operating loss	(14,328)	(5,250)	(9,078)	172.9 %	(25,487)	(3,670)	(21,817)	594.5 %
Interest expense	1,569	2,808	(1,239)	(44.1)%	6,224	6,668	(444)	(6.7)%
Gain on extinguishment of debt	—	—	—	N/A	(889)	—	(889)	N/A
Other loss (income)	3,940	(596)	4,536	(761.1)%	3,209	(1,702)	4,911	(288.5)%
Loss before income taxes	(19,837)	(7,462)	(12,375)	165.8 %	(34,031)	(8,636)	(25,395)	294.1 %
Income tax (benefit) expense	(6,422)	(1,076)	(5,346)	496.8 %	(2,967)	1,425	(4,392)	(308.2)%
Net loss	$ (13,415)	$ (6,386)	$ (7,029)	110.1 %	$ (31,064)	$ (10,061)	$ (21,003)	208.8 %

Comparison of the Periods Ended September 30, 2021 and 2020

Revenues

We classify our revenues into three product categories: precision diagnostics, radiopharmaceutical oncology, and strategic partnerships and other. Precision diagnostics includes DEFINITY, TechneLite and other imaging diagnostic products. Radiopharmaceutical oncology consists primarily of PYLARIFY and AZEDRA. Strategic partnerships and other includes partnerships related to other products of the Company, such as RELISTOR, that improve patient outcomes and care.

Revenues are summarized by product category on a net basis as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	**2021**	**2020[1]**	**Change $**	**Change %**	**2021**	**2020**	**Change $**	**Change %**
DEFINITY	$ 57,636	$ 50,359	$ 7,277	14.5 %	$ 173,448	$ 139,989	$ 33,459	23.9 %
TechneLite	22,680	21,113	1,567	7.4 %	69,252	62,560	6,692	10.7 %
Other precision diagnostics	7,563	8,585	(1,022)	(11.9)%	21,289	28,782	(7,493)	(26.0)%
Total precision diagnostics	87,879	80,057	7,822	9.8 %	263,989	231,331	32,658	14.1 %
Radiopharmaceutical oncology	8,890	3,323	5,567	167.5 %	13,203	7,474	5,729	76.7 %
Strategic partnerships and other	5,304	5,164	140	2.7 %	18,454	6,453	12,001	186.0 %
Total revenues	$ 102,073	$ 88,544	$ 13,529	15.3 %	$ 295,646	$ 245,258	$ 50,388	20.5 %

(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.

The increase in revenues for the three months ended September 30, 2021, as compared to the prior year period, is primarily driven by increases in DEFINITY and TechneLite volume period over period as a result of the COVID-19 pandemic in the prior year and the commercial launch of PYLARIFY, offset, in part, by the divestiture of our Puerto Rico business during the first quarter of 2021.

The increase in revenues for the nine months ended September 30, 2021, as compared to the prior year period, is primarily driven by increases in DEFINITY and TechneLite volume period over period as a result of the COVID-19 pandemic in the prior year, the addition of the Progenics product portfolio, including the commercial launch of PYLARIFY. This increase is partially offset by continued COVID-19 related reduced volumes in Xenon and the divestiture of our Puerto Rico business during the first quarter of fiscal year 2021.

Rebates and Allowances

Estimates for rebates and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to revenue and the establishment of a liability which is included in accrued expenses. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for our products, administrative fees of group purchasing organizations and certain distributor related commissions. The calculation of the accrual for these rebates and allowances is based on an estimate of the third-party's buying patterns and the resulting applicable contractual rebate to be earned over a contractual period.

An analysis of the amount of, and change in, reserves is summarized as follows:

(in thousands)	**Rebates and Allowances**
Balance, January 1, 2021	$ 9,350
Provision related to current period revenues	19,459
Adjustments relating to prior period revenues	(33)
Payments or credits made during the period	(19,361)
Balance, September 30, 2021	$ 9,415

Gross Profit

The increase in gross profit for the three months ended September 30, 2021, as compared to the prior year period is primarily due to DEFINITY volume increases and PYLARIFY post commercial launch volume increases, which are partially offset by amortization expense of assets acquired in the Progenics Acquisition.

The increase in gross profit for the nine months ended September 30, 2021, as compared to the prior year period is primarily due to DEFINITY volume increases and an asset impairment loss of $7.3 million on other nuclear products that occurred in the prior year. This increase was offset, in part, by lower Xenon unit volumes and increased radioisotope transportation costs, both due to COVID-19, as well as amortization expense of assets acquired in the Progenics Acquisition.

Sales and Marketing

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in field sales, marketing and customer service functions. Other costs in sales and marketing expenses include the development and printing of advertising and promotional material, professional services, market research and sales meetings.

Sales and marketing expenses increased $5.6 million and $21.0 million for the three and nine months ended September 30, 2021, respectively, as compared to the prior year period. This was primarily driven by the integration of the Progenics sales and marketing organization, preparation activities for the launch of PYLARIFY and increased employee-related costs, as well as the reduced level of marketing promotional programs during the prior year due to the impact of the COVID-19 pandemic.

General and Administrative

General and administrative expenses consist of salaries and other related costs for personnel in executive, finance, legal, information technology and human resource functions. Other costs included in general and administrative expenses are professional fees for information technology services, external legal fees, consulting and accounting services as well as bad debt expense, certain facility and insurance costs, including director and officer liability insurance.

General and administrative expenses increased $10.3 million for the three months ended September 30, 2021 compared to the prior period. This was primarily driven by the $9.5 million sublease impairment charge and $2.6 million fair value adjustment to the contingent asset and liabilities in the third quarter of 2021 (an increase of $1.8 million from the prior year period) (refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities, including CVRs), offset by acquisition-related costs associated with the Progenics Acquisition in the prior year.

General and administrative expenses increased $32.3 million for the nine months ended September 30, 2021 compared to the prior year period. This was primarily driven by the $28.5 million fair value adjustment to the contingent asset and liabilities (an increase of $27.7 million from the prior year period), $9.5 million sublease impairment charge and higher headcount related costs following the Progenics Acquisition, offset by acquisition-related costs associated with the Progenics Acquisition in the prior year and synergy capture in the current year.

Research and Development

Research and development expenses relate primarily to the development of new products to add to our portfolio and costs related to our medical affairs, medical information and regulatory functions.

Research and development expenses decreased $0.4 million for the three months ended September 30, 2021 as compared to the prior year period. This was primarily driven by the filing fee related to the PYLARIFY New Drug Application and preparation activities for the launch of PYLARIFY during the prior year period; offset by phasing of the ARROW Phase 2 study of 1095 and higher overall headcount related costs.

Research and development expenses increased $13.5 million for the nine months ended September 30, 2021 as compared to the prior year period. This was primarily driven by the integration of the Progenics research and development organization now supporting our pipeline, which includes 1095, preparation activities for the launch of PYLARIFY and higher employee-related costs due to the impact of the COVID-19 pandemic during the prior year period; offset by the filing fee related to the PYLARIFY New Drug Application during the prior year period.

Gain on Sale of Assets

We sold 100% of the stock of our Puerto Rico radiopharmacy subsidiary resulting in a pre-tax book gain of $15.3 million for the nine months ended September 30, 2021.

Interest Expense

Interest expense decreased by approximately $0.4 million for the nine months ended September 30, 2021 as compared to the prior year period due to lower interest rates on our long-term debt.

Gain on Extinguishment of Debt

For the nine months ended September 30, 2021, we realized a $0.9 million gain on extinguishment of debt related to the voluntary repayment of the outstanding principal on the Royalty-Backed Loan on March 31, 2021.

Income Tax (Benefit) Expense

The income tax benefit recorded for the three months ended September 30, 2021 was primarily due to the tax benefit of a release of uncertain tax position liability, and a pre-tax loss reported during the quarter partially offset by the accrual of interest associated with uncertain tax positions.

The income tax benefit recorded for the nine months ended September 30, 2021 was primarily due to the tax benefit of released of uncertain tax position liabilities and the pre-tax loss reported during the period, partially offset by the accrual of interest associated with uncertain tax positions and the impact of permanent item adjustments including the accrual of contingent consideration liabilities.

We regularly assess our ability to realize our deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether our deferred tax assets are more-likely-than-not realizable, we evaluate all available positive and negative evidence, and weigh the objective evidence and expected impact. We continue to record a valuation allowance against certain of our foreign net deferred tax assets and a small component of our domestic deferred tax assets.

Our effective tax rate for each reporting period is presented as follows:

	Nine Months Ended September 30,	
	2021	**2020**
Effective tax rate	8.7%	(16.5)%

Our effective tax rate in fiscal 2021 differs from the U.S. statutory rate of 21% principally due to releases of uncertain tax position liabilities and the impact of non-deductible contingency reserve expense.

The decrease in the effective income tax rate for the nine months ended September 30, 2021 is primarily due to the reduction in tax benefit resulting from the accrual of non-deductible contingency reserve expense.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

	Nine Months Ended September 30,	
(in thousands)	2021	2020
Net cash provided by operating activities	$ 40,027	$ 15,827
Net cash provided by (used in) investing activities	$ 8,227	$ (1,127)
Net cash used in financing activities	$ (37,232)	$ (17,488)

Net Cash Provided by Operating Activities

Net cash provided by operating activities of $40.0 million in the nine months ended September 30, 2021 was driven primarily by depreciation, amortization and accretion expense of $30.1 million, a change in fair value of contingent assets and liabilities of $28.5 million (refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities, including CVRs), stock-based compensation expense of $11.8 million, impairment of long-lived assets of $9.5 million and a net increase of $2.4 million related to movements in our working capital accounts during the period. The overall increases in cash from our working capital accounts were primarily driven by an increase in sales collections, the timing of payments to large vendors, and an increase in fees related to PYLARIFY sales. These net sources of cash were offset by a net loss of $31.1 million and a gain on sale of assets of $15.3 million.

Net cash provided by operating activities of $15.8 million in the nine months ended September 30, 2020 was driven primarily by $16.3 million of depreciation, amortization and accretion expense, stock-based compensation expense of $10.5 million, and impairment of long-lived assets of $7.3 million. These net sources of cash were offset by a net loss of $10.1 million and a net decrease of $11.7 million related to movements in our working capital accounts during the period. The overall decreases in cash from our working capital accounts were primarily driven by the payment of prior year annual bonuses as well as change in inventory related to the COVID-19 impact on products and the timing of batch processes and accruals related to general and administrative expenses in connection with the acquisition of Progenics.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2021 was primarily due to cash proceeds of $15.8 million received from the sale of our Puerto Rico subsidiary, which was offset by $7.6 million of capital expenditures.

Net cash used in investing activities during the nine months ended September 30, 2020 reflected $10.0 million in lending on a note receivable to Progenics prior to the acquisition and $8.7 million in capital expenditures offset by $17.6 million of acquired cash related to the non-cash Progenics Acquisition.

Net Cash Used in Financing Activities

Net cash used in financing activities during the nine months ended September 30, 2021 is primarily attributable to the payments on long-term debt and other borrowings of $40.8 million related to the 2019 Term Facility and Royalty-Backed Loan, including a voluntary repayment of the outstanding principal on the Royalty-Backed Loan and payments for minimum statutory tax withholding related to net share settlement of equity awards of $1.9 million offset by proceeds of $4.6 million from stock option exercises.

Net cash used in financing activities during the nine months ended September 30, 2020 is primarily attributable to the payments on long-term debt and other borrowings of $11.2 million related to the 2019 Term Facility and Royalty-Backed Loan, equity issuance costs related to the acquisition of Progenics of $3.8 million, and payments for minimum statutory tax withholding related to net share settlement of equity awards of $2.1 million.

External Sources of Liquidity

In June 2019, we refinanced our 2017 $275.0 million five-year term loan facility with the 2019 Term Facility. In addition, we replaced our $75.0 million revolving facility with our five-year revolving credit facility (the “2019 Revolving Facility” and, together with the 2019 Term Facility, the “2019 Facility”). The terms of the 2019 Facility are set forth in the Credit Agreement, dated as of June 27, 2019, by and among us, the lenders from time to time party thereto and Wells Fargo Bank, N.A., as administrative agent and collateral agent. We have the right to request an increase to the 2019 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $100.0 million, plus additional amounts, in certain circumstances.

We are permitted to voluntarily repay the 2019 Term Loans, in whole or in part, without premium or penalty. The 2019 Term Facility requires us to make mandatory prepayments of the outstanding 2019 Term Loans in certain circumstances. The 2019 Term Facility amortizes at 5.0% per year through September 30, 2022 and 7.5% thereafter, until its June 27, 2024 maturity date.

Under the terms of the 2019 Revolving Facility, the lenders thereunder agreed to extend credit to us from time to time until June 27, 2024 consisting of revolving loans in an aggregate principal amount not to exceed $200.0 million at any time outstanding. The 2019 Revolving Facility includes a $20.0 million sub-facility for the issuance of Letters of Credit. The 2019 Revolving Facility includes a $10.0 million sub-facility for Swingline Loans. The Letters of Credit, Swingline Loans and the borrowings under the 2019 Revolving Facility are expected to be used for working capital and other general corporate purposes.

Please refer to our Form 10-K for fiscal year ended December 31, 2020 for further details on the 2019 Facility.

On June 19, 2020, we amended our 2019 Credit Agreement (the “Amendment”) as a result of the impact of the COVID-19 pandemic on our business and operations and the near-term higher level of indebtedness resulting from our decision not to immediately repay the Progenics debt secured by the RELISTOR royalties following the Progenics Acquisition.

The Amendment provides for, among other things, modifications to our financial maintenance covenants. The covenant related to Total Net Leverage Ratio (as defined in the Amended Credit Agreement) was waived from the date of the Amendment through December 31, 2020. The maximum total net leverage ratio and interest coverage ratio permitted by the financial covenant is displayed in the table below:

2020 Amended Credit Agreement

Period	Total Net Leverage Ratio
Q3 2021 and Thereafter	3.50 to 1.00

Period	Interest Coverage Ratio
Q2 2021 and thereafter	3.00 to 1.00

As of September 30, 2021, we were in compliance with all financial and other covenants under the Amendment.

For the period beginning on the date of the Amendment and ending on the Adjustment Date (as defined in the Amended Credit Agreement) for the fiscal quarter ending March 31, 2021, loans under the Amended Credit Agreement bear interest at LIBOR plus 3.25% or the Base Rate plus 2.25%. On and after the Adjustment Date for the fiscal quarter ending on March 31, 2021, loans bear interest at LIBOR plus a spread that ranges from 1.50% to 3.00% or the Base Rate plus a spread that ranges from 0.50% to 2.00%, in each case based on our Total Net Leverage Ratio.

The commitment fee applicable to the Revolving Facility was 0.50% until the Adjustment Date for the fiscal quarter ending March 31, 2021. On and after the Adjustment Date for the fiscal quarter ending on March 31, 2021, the commitment fee ranges from 0.15% to 0.40% based on our Total Net Leverage Ratio.

On June 19, 2020, as a result of the Progenics Acquisition, we assumed Progenics outstanding debt as of such date in the amount of $40.2 million. Progenics, through a wholly-owned subsidiary MNTX Royalties Sub LLC (“MNTX Royalties”), entered into a $50.0 million loan agreement (the “Royalty-Backed Loan”) with a fund managed by HealthCare Royalty Partners III, L.P. (“HCRP”) on November 4, 2016. Under the terms of the Royalty-Backed Loan, the lenders had no recourse to Progenics or any of its assets other than the right to receive royalty payments from the commercial sales of RELISTOR products owed under Progenics’ license agreement with Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch. The RELISTOR royalty payments were used to repay the principal and interest on the loan. The Royalty-Backed Loan bore interest at a per annum rate of 9.5% and was scheduled to mature on June 30, 2025. On June 22, 2020, HCRP waived the automatic acceleration of the Royalty-Backed Loan that otherwise would have been triggered by the consummation of the Progenics Acquisition and MNTX Royalties agreed not to prepay the loan until after December 31, 2020.

On March 31, 2021, we voluntarily repaid in full the entire outstanding principal on the Royalty-Backed Loan in the amount of $30.9 million, which included a prepayment amount of $0.5 million, and terminated the agreement.

Our ability to fund our future capital needs will be affected by our ability to continue to generate cash from operations and may be affected by our ability to access the capital markets, money markets or other sources of funding, as well as the capacity and terms of our financing arrangements.

We may from time to time repurchase or otherwise retire our debt and take other steps to reduce our debt or otherwise improve our balance sheet. These actions may include prepayments of our term loans or other retirements or refinancing of outstanding debt, privately negotiated transactions or otherwise. The amount of debt that may be retired, if any, could be material and would be decided at the sole discretion of our Board of Directors and will depend on market conditions, our cash position and other considerations.

Funding Requirements

Our future capital requirements will depend on many factors, including:

- The level of product sales and the pricing environment of our currently marketed products, particularly DEFINITY and any additional products that we may market in the future, including decreased product sales resulting from the COVID-19 pandemic;
- Revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers and additional competition;
- The costs of the PYLARIFY commercial launch and our ability to successfully commercialize PYLARIFY;
- The costs of acquiring or in-licensing, developing, obtaining regulatory approval for, and commercializing, new products, businesses or technologies, together with the costs of pursuing opportunities that are not eventually consummated;
- Our investment in the further clinical development and commercialization of products and development candidates, including AZEDRA, PYLARIFY, 1095, LMI 1195, aBSI and PSMA AI;
- The costs of investing in our facilities, equipment and technology infrastructure;
- The costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our products and raw materials and components;
- Our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future, including our ability to negotiate a new manufacturing agreement with JHS for DEFINITY, or to begin and ramp up our manufacturing of DEFINITY at our in-house manufacturing facility in an amount sufficient to meet our supply needs;
- The costs of further commercialization of our existing products, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
- The extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products;
- The legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- The cost of interest on any additional borrowings which we may incur under our financing arrangements.

Until we successfully become dual sourced for our principal products, we are vulnerable to future supply shortages. Disruption in our financial performance could also occur if we experience significant adverse changes in product or customer mix, broad economic downturns, adverse industry or company conditions or catastrophic external events, including pandemics such as COVID-19, natural disasters and political or military conflict. If we experience one or more of these events in the future, we may be required to further implement expense reductions, such as a delay or elimination of discretionary spending in all functional areas, as well as scaling back select operating and strategic initiatives.

If our capital resources become insufficient to meet our future capital requirements, we would need to finance our cash needs through public or private equity offerings, debt financings, assets securitizations, sale-leasebacks or other financing or strategic alternatives, to the extent such transactions are permissible under the covenants of our Credit Agreement. Additional equity or debt financing, or other transactions, may not be available on acceptable terms, if at all. If any of these transactions require an amendment or waiver under the covenants in our Credit Agreement, which could result in additional expenses associated with obtaining the amendment or waiver, we will seek to obtain such a waiver to remain in compliance with those covenants. However, we cannot be assured that such an amendment or waiver would be granted, or that additional capital will be available on acceptable terms, if at all.

At September 30, 2021, our only current committed external source of funds is our borrowing availability under our 2019 Revolving Facility. We had $91.5 million of cash and cash equivalents at September 30, 2021. Our 2019 Facility, as amended, contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the 2019 Revolving Facility, as amended, may affect our ability to comply with the covenants in the 2019 Facility, as amended, including the financial covenants restricting consolidated net leverage and interest coverage. Accordingly, we may be limited in utilizing the full amount of our 2019 Revolving Facility, as amended, as a source of liquidity.

The CVRs we issued in the Progenics Acquisition entitle holders thereof to future cash payments of 40% of PYLARIFY net sales over (i) $100.0 million in 2022 and (ii) $150.0 million in 2023, which, if payable, we currently intend to fund from our then-available cash. In no event will our aggregate payments under the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% (which we estimate could be approximately $100.0 million) of the total consideration we pay in the Progenics Acquisition. Refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities.

Based on our current operating plans, including our prudent expense management in response to the COVID-19 pandemic, we believe that our existing cash and cash equivalents, results of operations and availability under our 2019 Revolving Facility, as amended, will be sufficient to continue to fund our liquidity requirements for the foreseeable future.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ materially from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

There have been no other significant changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the nine months ended September 30, 2021. For further information, refer to our summary of significant accounting policies and estimates in our Annual Report on Form 10-K filed for the year ended December 31, 2020.

Off-Balance Sheet Arrangements

We are required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating our ability to fund the decommissioning of our North Billerica, Massachusetts production facility upon closure, though we do not intend to close the facility. We have provided this financial assurance in the form of a $28.2 million surety bond.

Since inception, we have not engaged in any other off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk, see Part II, Item 7A. “Quantitative and Qualitative Disclosures About Market Risk,” of our Annual Report on Form 10-K for the year ended December 31, 2020. Our exposures to market risk have not changed materially since December 31, 2020.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

The Company’s management, with the participation of the Company’s Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), its principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of the Company’s disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation, the Company’s CEO and CFO concluded that the Company’s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) were effective as of the period covered by this report.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We are continually monitoring and assessing the pandemic status to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Information with respect to certain legal proceedings is included in Note 19, “Commitments and Contingencies”, to the condensed consolidated financial statements contained in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Item 1A. Risk Factors

There have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, except as set forth below:

The near-term growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other existing echocardiography agents and potential generic competitors.

The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. There were approximately 31.5 million echocardiograms in 2020 according to a third-party source. Assuming 20% of echocardiograms produce suboptimal images, as stated in the clinical literature, we estimate that approximately 6.3 million echocardiograms in 2020 produced suboptimal images. We estimate that DEFINITY held over 80% of the U.S. market for ultrasound enhancing agents in echocardiography procedures as of December 31, 2020. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a Bracco Diagnostics Inc. (“Bracco”) product (known as SonoVue outside the U.S.), as well as echocardiography without ultrasound enhancing agents and other non-echocardiography agents.

We launched DEFINITY in 2001, and we continue to actively pursue additional patents in connection with DEFINITY and DEFINITY RT, both in the U.S. and internationally. In the U.S. for DEFINITY we now own a total of four Orange Book-listed method of use patents, one of which expires in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. In the U.S. for DEFINITY RT, we own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY patent protection and regulatory exclusivity have generally expired, we are currently prosecuting additional DEFINITY and DEFINITY RT patents to obtain similar patent protection as in the U.S. The Orange Book-listed patents include a patent on the use of VIALMIX RFID, which expires in 2037; additional VIALMIX RFID patent applications have been submitted in major markets throughout the world.

Because our Orange Book-listed composition of matter patent expired in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve ANDAs for generic versions of drugs before the expiration of an Orange Book-listed patent covering the innovator product if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent or that an Orange Book-listed patent is invalid. The ANDA applicant must also give Notice to the innovator, which would then enable the innovator to challenge the ANDA applicant in court within 45 days of receiving such Notice. If the innovator challenges the ANDA applicant in court in a timely manner, then FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months while the dispute between the innovator and the ANDA applicant is resolved in court. The 30 month stay can be shortened if the patent infringement suit is resolved in the ANDA applicant’s favor before the 30 month stay expires, and this may involve a successful challenge of the patent’s validity in USPTO proceedings and appeals process.

As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any such Notice from any ANDA applicant, but we can give no assurance that we will not receive a Notice in the future. If we were to receive any such Notice in the future, we would review the Notice, evaluate the strength of any potential patent infringement claims, and be prepared to challenge the ANDA applicant in a timely fashion, which would thereby trigger the stay of up to 30 months. We can give no assurance that we would have grounds to file a patent infringement suit, that we would obtain the full 30 month stay, that we would be successful on the merits asserting that a generic candidate infringes our Orange Book-listed patent, or that we would be successful defending the validity of our Orange Book-listed patent in court or in a USPTO adversarial proceeding. In addition, as discussed in our risk factor “Our business and industry are subject to complex and costly regulations. If government regulations are interpreted or enforced in a manner adverse to us or our business, we may be subject to enforcement actions, penalties, exclusion and other material limitations on our operations.”set forth below, if the FDA reclassified one or more of our imaging agents, such as DEFINITY, as a “device” rather than a “drug”, we do not know when such reclassification would become effective, how any transition rules would be formulated or applied, and whether or not the legal framework provided by the Hatch-Waxman Act would be preserved for some time after such reclassification.

As part of our microbubble franchise strategy, (i) we have developed and received FDA approval for DEFINITY RT, a modified formulation of DEFINITY, (ii) we look for other opportunities to expand our microbubble franchise, including new applications beyond echocardiography and ultrasound enhancing agent imaging generally such as our strategic arrangements with Cerevast, CarThera and Insightec, and (iii) we have completed construction of our specialized in-house manufacturing capabilities at our North Billerica facility for DEFINITY and, potentially, other sterile vial products. However, we can give no assurance that our microbubble franchise strategy will be successful or that a modified formulation, new applications or new manufacturing capabilities will grow our microbubble franchise.

We believe DEFINITY RT will become commercially available in the fourth quarter of 2021, although that timing cannot be assured.

If we are not able to continue to (i) grow DEFINITY and DEFINITY RT sales, which depend on one or more of the growth of echocardiograms, the growth in the appropriate use of ultrasound enhancing agents in suboptimal echocardiograms, and our ability to sustain and grow our leading position in the U.S. echocardiography ultrasound enhancing agent market, or (ii) be successful with our microbubble franchise strategy, we may not be able to continue to grow the revenue and cash flow of our business, which could have a negative effect on our business, results of operations and financial condition.

Our dependence upon third parties for the manufacture and supply of a substantial portion of our products could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues.

We obtain a substantial portion of our products from third party manufacturers and suppliers. We rely on JHS as our sole source manufacturer of DEFINITY, NEUROLITE, Cardiolite and evacuation vials. We rely on SBL as our sole source manufacturer of DEFINITY RT.

Based on our current estimates, we believe that we will have sufficient supply of DEFINITY, NEUROLITE, Cardiolite and evacuation vials from JHS, and sufficient supply of saline from our sole manufacturer, to meet expected demand. However, we can give no assurances that JHS or our other manufacturing partner will be able to manufacture and distribute our products in a high quality and timely manner and in sufficient quantities to allow us to avoid product stock-outs and shortfalls. In addition, on July 27, 2021, we received a letter from JHS that it was providing notice of non-renewal of our manufacturing agreement relating to DEFINITY, but that JHS remained interested in negotiating a new agreement. We are actively negotiating a new manufacturing agreement with JHS for DEFINITY, although there is no assurance that we will be able to reach an agreement on mutually acceptable terms or at all. In the event we are not able to enter into an agreement on mutually acceptable terms or at all, we expect that we would exercise our right under our current agreement with JHS to request a terminal supply of DEFINITY in an amount sufficient to meet our supply needs for DEFINITY until our in-house manufacturing facility is operational and producing enough DEFINITY to meet our supply needs, although there is no assurance that there would be no disruption.

Xenon is captured as a by-product of the Mo-99 production process. We receive bulk unprocessed Xenon from IRE resulting from highly-enriched uranium (“HEU”) Mo-99 production, which we process and finish for our customers. We do not yet receive Xenon resulting from low-enriched uranium (“LEU”) Mo-99 production at IRE and can give no assurances as to the timing of the availability of LEU Xenon. We believe we will have a sufficient supply of Xenon to meet our customers’ needs. However, until IRE converts to LEU Xenon production or we can qualify an additional source of bulk unprocessed Xenon, we will rely on IRE as a sole source provider of HEU Xenon.

1095 is currently manufactured only at the Center for Probe Development and Commercialization (“CPDC”). Until December 2019, the CPDC was subject to an Import Alert by the FDA, which restricted the CPDC’s ability to ship products to the U.S. Although the CPDC has since been cleared by the FDA to ship products to the U.S., there can be no guarantee that the CPDC, or any other third-party manufacturer that we may partner with in the future, will not be subject to similar restrictions in the future.

In addition to the products described above, for reasons of quality assurance or cost-effectiveness, we purchase certain components and raw materials from sole suppliers (including, for example, the lead casing for our TechneLite generators and the lipid blend material used in the processing of DEFINITY). Because we do not control the actual production of many of the products we sell and many of the raw materials and components that make up the products we sell, we may be subject to delays caused by interruption in production based on events and conditions outside of our control. At our North Billerica, Massachusetts facility, we manufacture TechneLite on a highly automated production line, as well as Thallium and Gallium using our older cyclotron technology and Xenon using our hot cell infrastructure. As with all manufacturing facilities, equipment and infrastructure age and become subject to increasing maintenance and repair. If we or one of our manufacturing partners experiences an event, including a labor dispute, natural disaster, fire, power outage, machinery breakdown, security problem, failure to meet regulatory requirements, product quality issue, technology transfer issue or other issue, we may be unable to manufacture the relevant products at previous levels or on the forecasted schedule, if at all. Due to the stringent regulations and requirements of the governing regulatory authorities regarding the manufacture of our products, we may not be able to quickly restart manufacturing at a third party or our own facility or establish additional or replacement sources for certain products, components or materials.

In addition to our existing manufacturing relationships, we are also pursuing new manufacturing relationships to establish and secure additional or alternative suppliers for our commercial products. We have also completed construction of our specialized in-house manufacturing capabilities at our North Billerica, Massachusetts facility. This project should not only deliver efficiencies and supply chain redundancy for our current portfolio but also should afford us increased flexibility as we consider external opportunities. However, we cannot assure you that these activities or any of our additional supply activities will be successful or that we will be able to avoid or mitigate interim supply shortages before new sources of product are fully functional and qualified. In addition, we cannot assure you that our existing manufacturers or suppliers or any new manufacturers or suppliers can

adequately maintain either their financial health, technical capabilities or regulatory compliance to allow continued production and supply. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could eventually have a material adverse effect on our business, results of operations, financial condition and cash flows.

Our business and industry are subject to complex and costly regulations. If government regulations are interpreted or enforced in a manner adverse to us or our business, we may be subject to enforcement actions, penalties, exclusion and other material limitations on our operations.

Both before and after the approval of our products and agents in development, we, our products, development agents, operations, facilities, suppliers, distributors, contract manufacturers, contract research organizations and contract testing laboratories are subject to extensive and, in certain circumstances, expanding regulation by federal, state and local government agencies in the U.S. as well as non-U.S. and transnational laws and regulations, with regulations differing from country to country, including, among other things, anti-trust and competition laws and regulations and the recently enacted General Data Protection Regulation in the European Union. In the U.S., the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale, distribution, and import and export of drug products. We are required to register our business for permits and/or licenses with, and comply with the stringent requirements of the FDA, the U.S. Nuclear Regulatory Commission, the U.S. Department of Health and Human Services, Health Canada, the European Medicines Agency, the U.K. Medicines and Healthcare Products Regulatory Agency, the NMPA, state and provincial boards of pharmacy, state and provincial health departments and other federal, state and provincial agencies. Violation of any of these regulatory schemes, individually or collectively, could disrupt our business and have a material adverse effect on our business, results of operations, financial condition and cash flows.

Under U.S. law, for example, we are required to report certain adverse events and production problems, if any, to the FDA. We also have similar adverse event and production reporting obligations outside of the U.S., including to the EMA and MHRA. Additionally, we must comply with requirements concerning advertising and promotion for our products, including the prohibition on the promotion of our products for indications that have not been approved by the FDA or a so-called “off-label use” or promotion that is inconsistent with the approved labeling. If the FDA determines that our promotional materials constitute unlawful promotion, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions. Also, quality control and manufacturing procedures at our own facility and at third party suppliers must conform to cGMP regulations and other applicable law after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs and other applicable law, and, from time to time, makes those cGMPs more stringent. Accordingly, we and others with whom we work must expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. If in the future issues arise at a third party manufacturer, the FDA could take regulatory action which could limit or suspend the ability of that third party to manufacture our products or have any additional products approved at the relevant facility for manufacture until the issues are resolved and remediated. Such a limitation or suspension could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We are also subject to laws and regulations that govern financial and other arrangements between pharmaceutical manufacturers and healthcare providers, including federal and state anti-kickback statutes, federal and state false claims laws and regulations, federal and state “sunshine” laws and regulations and other fraud and abuse laws and regulations.

We must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid drug rebate program, the “federal ceiling price” drug pricing program, the 340B drug pricing program and the Medicare Part D Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid drug rebate program and Medicare Part B. As a specific example, in 2010, we entered into a Medicaid Drug Rebate Agreement with the federal government for some but not all of our products, and in 2016 entered into a separate Medicaid Drug Rebate Agreement for the balance of our products. These agreements require us to report certain price information to the federal government. Determination of the rebate amount that we pay to state Medicaid programs for our products, of prices charged to government and certain private payors for our products, or of amounts paid for our products under government healthcare programs, depends upon information reported by us to the government. If we provide customers or government officials with inaccurate information about the products’ pricing or eligibility for coverage, or the products fail to satisfy coverage requirements, we could be terminated from the rebate program, be excluded from participation in government healthcare programs, or be subject to potential liability under the False Claims Act or other laws and regulations.

Failure to comply with other requirements and restrictions placed upon us or our third party manufacturers or suppliers by laws and regulations can result in fines, civil and criminal penalties, exclusion from federal healthcare programs and debarment. Possible consequences of those actions could include:

- Substantial modifications to our business practices and operations;
- Significantly reduced demand for our products (if products become ineligible for reimbursement under federal and state healthcare programs);

- A total or partial shutdown of production in one or more of the facilities where our products are produced while the alleged violation is being remediated;
- Delays in or the inability to obtain future pre-market clearances or approvals; and
- Withdrawals or suspensions of our current products from the market.

Regulations are subject to change as a result of legislative, administrative or judicial action, which may also increase our costs or reduce sales or otherwise adversely impact our products. For example, on April 16, 2021 in the case Genus Medical Technologies LLC v. Food and Drug Administration, the U.S. Court of Appeals for the D.C. Circuit held that a product (other than a combination product) that meets the definitions of both "drug" and "device" in the Federal Food, Drug, and Cosmetic Act (the "FDCA") must be regulated as a device. On August 9, 2021, the FDA announced that, as part of its implementation of this court decision, the FDA intends to regulate products that meet both the device and drug definition as devices, except where Congress intended a different classification. The FDA further indicated that it intends to bring previously classified products into line with the court decision and will reexamine whether individual imaging agents meet the device definition. In connection with its announcement, the FDA requested comments from the industry on five topics: categories of products implicated by the court decision; the transition process; the transition timing; user fee transitions; and determining drug or device status. We plan to submit comments to the FDA in response to its request for comments by the November 30, 2021 deadline. While we question whether the FDA has authority to make this change, believe that pre-existing law already establishes that a broad spectrum of imaging agents have already been established by Congress to be "drugs", and do not believe that any of our imaging agents meets the definition of a "device" under the FDCA, we can give no assurance that the FDA will agree with our position. In addition, if the FDA determines that one or more of our imaging agents meet the definition of a "device", we do not know when such reclassification would be effective, how any transition rules would be formulated or applied, and whether or not the legal framework provided by the Hatch-Waxman Act would be preserved for some time after such reclassification. A reclassification of one or more of our imaging agents as a "device" could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Ultrasound enhancing agents may cause side effects which could limit our ability to sell DEFINITY.

DEFINITY is an ultrasound enhancing agent based on perflutren lipid microspheres. In 2007, the FDA received reports of deaths and serious cardiopulmonary reactions following the administration of ultrasound micro-bubble enhancing agents used in echocardiography. Four of the 11 reported deaths were caused by cardiac arrest occurring either during or within 30 minutes following the administration of the ultrasound enhancing agent; most of the serious but non-fatal reactions also occurred in this time frame. As a result, in October 2007, the FDA requested that we and GE Healthcare, which distributes Optison, a competitor to DEFINITY, add a boxed warning to these products emphasizing the risk for serious cardiopulmonary reactions and that the use of these products was contraindicated in certain patients. In a strong reaction by the cardiology community to the FDA's new position, a letter was sent to the FDA, signed by 161 doctors, stating that the benefit of these ultrasound enhancing agents outweighed the risks and urging that the boxed warning be removed. In May 2008, the FDA substantially modified the boxed warning. On May 2, 2011, the FDA held an advisory committee meeting to consider the status of ultrasound micro-bubble contrast agents and the boxed warning. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section "The safety and efficacy of DEFINITY with exercise stress or pharmacologic stress testing have not been established" (previously added in October 2007 in connection with the imposition of the box warning); and including summary data from the post-approval CaRES (Contrast echocardiography Registry for Safety Surveillance) safety registry and the post-approval pulmonary hypertension study. Further, in January 2017, the FDA approved an additional modification to the DEFINITY label, removing the contraindication statement related to use in patients with a known or suspected cardiac shunt. Bracco's ultrasound enhancing agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. In April 2021, after reviewing certain adverse events that occurred in patients with a prior history of allergic reactions to polyethylene glycol ("PEG"), an inactive excipient in both DEFINITY and Lumason, the FDA and the marketing authorization holders of these products agreed to an additional contraindication for use of these products, including advising clinicians to assess patients for prior PEG hypersensitivity before administering these products. If additional safety issues arise (not only with DEFINITY but also potentially with Optison and Lumason), this may result in unfavorable changes in labeling or result in restrictions on the approval of our product, including removal of the product from the market. Lingering safety concerns about DEFINITY among some healthcare providers or future unanticipated side effects or safety concerns associated with DEFINITY could limit expanded use of DEFINITY and have a material adverse effect on the unit sales of this product and our financial condition and results of operations.

In the U.S., we are heavily dependent on a few large customers to generate a majority of our revenues for our nuclear medical imaging products. Outside of the U.S., we rely primarily on distributors to generate a substantial portion of our revenue.

In the U.S., we have historically relied on a limited number of radiopharmacy customers, primarily Cardinal, RLS, UPPI, Jubilant Radiopharma and PharmaLogic, to distribute our current largest volume nuclear imaging products. Among the existing radiopharmacies in the U.S., continued consolidations, divestitures and reorganizations may have a negative effect on our business, results of operations, financial condition and cash flows. We generally have distribution arrangements with our major radiopharmacy customers pursuant to multi-year contracts, each of which is subject to renewal. Recently, we extended our contract with Jubilant Radiopharma with respect to certain products, other than TechneLite and Thallium-201, through December 31, 2023. If these contracts are terminated prior to the expiration of their term, or are not renewed, or are renewed on terms that are less favorable to us, then such an event could have a material adverse effect on our business, results of operations, financial condition and cash flows.

For all of our medical imaging products, we continue to experience significant pricing pressures from our competitors, large customers and group purchasing organizations, and any significant, additional pricing pressures could lead to a reduction in revenue which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Outside of the U.S. and Canada, we have no sales force and, consequently, rely on third-party distributors, either on a country-by-country basis or on a multi-country, regional basis, to market, sell and distribute our products. In Canada, we maintain our own direct sales force to sell DEFINITY. In certain circumstances, distributors may also sell competing products to our own or products for competing diagnostic modalities and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain current levels of unit sales or that we will be able to increase or maintain our current unit pricing, which, in turn, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

The CVRs we issued as part of the Progenics Acquisition may result in substantial future payments and could divert the attention of our management; in addition, the actual payments made in connection with the CVRs, if any, may not be consistent with the estimated fair value of the CVRs that we are required to prepare for accounting purposes.

As part of the consideration for the Progenics Acquisition, we issued CVRs to the stockholders of Progenics and holders of in-the-money Progenics equity awards entitling them to future cash payments of 40% of PYLARIFY net sales over $100.0 million in 2022 and over $150.0 million in 2023. These payments could be substantial and could adversely impact our liquidity. In addition, we are obligated to exercise a level of effort, expertise and resources consistent with those normally used in a medical diagnostics business similar to our size and resources with respect to developing, seeking regulatory approval for and commercializing a product of similar market potential at a similar stage in its development or product life to PYLARIFY. We are also required to produce net sales statements for PYLARIFY that may be reviewed and challenged by CVR holders, with any disagreement to be resolved by an independent accountant. These requirements could divert management time and resources and result in additional costs.

Because the CVRs are considered contingent consideration liabilities, for accounting purposes we are required by U.S. GAAP to estimate their fair value on a recurring basis. Adjustments in the estimated fair value of the CVRs can impact our consolidated financial statements on a quarterly or annual basis. The estimated fair value of the CVRs is determined based on a Monte Carlo simulation model that include significant estimates and assumptions pertaining to commercialization events, sales targets, market conditions and discount rates. These estimates and assumptions are subject to the judgment of our management team and are not prepared with a view towards public disclosure of projected sales. Our sales targets are also subject to significant economic, competitive, industry and other uncertainties and contingencies, which are difficult to predict and in many cases are beyond our control. We can give no assurance that the actual amounts paid, if any, in connection with the CVRs will be consistent with any recurring fair value estimate for such CVRs.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Repurchases

The following table presents information with respect to purchases of common stock we made during the three months ended September 30, 2021. The Company does not currently have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, as amended on April 26, 2016 and as further amended on April 27, 2017, April 24, 2019 and April 28, 2021 (the "2015 Plan"), provides for the withholding of shares to satisfy minimum statutory tax withholding obligations. It does not specify a maximum number of shares that can be withheld for this purpose. The shares of common stock withheld to satisfy minimum tax withholding obligations may be deemed to be "issuer purchases" of shares that are required to be disclosed pursuant to this Item 2. These shares are then sold in compliance with Rule 10b5-1 into the market to allow the Company to satisfy the tax withholding requirements in cash.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
July 2021**	1,086	$ 26.20	*	*
August 2021**	1,077	$ 25.63	*	*
September 2021**	2,737	$ 25.61	*	*
Total	4,900		*	

* These amounts are not applicable as the Company does not have a share repurchase program in effect.

** Reflects shares withheld to satisfy minimum statutory tax withholding amounts due from employees related to the receipt of stock which resulted from the exercise or vesting of equity awards.

Dividend Policy

We did not declare or pay any dividends, and we do not currently intend to pay dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the foreseeable future, to finance the growth and development of our business and to repay indebtedness. Our ability to pay dividends is restricted by our financing arrangements. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-External Sources of Liquidity" for further information.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On July 27, 2021, we received a letter from JHS that it was providing notice of non-renewal of our manufacturing agreement relating to DEFINITY, but that JHS remained interested in negotiating a new agreement. We are actively negotiating a new manufacturing agreement with JHS for DEFINITY, although there is no assurance that we will be able to reach an agreement on mutually acceptable terms or at all. In the event we are not able to enter into an agreement on mutually acceptable terms or at all, we expect that we would exercise our right under our current agreement with JHS to request a terminal supply of DEFINITY in an amount sufficient to meet our supply needs for DEFINITY until our in-house manufacturing facility is operational and producing enough DEFINITY to meet our supply needs, although there can be no assurance that there would be no disruption.

Item 6. Exhibits

EXHIBIT NUMBER	DESCRIPTION OF EXHIBITS	INCORPORATED BY REFERENCE			
		FORM	FILE NUMBER	EXHIBIT	FILING DATE
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).				
32.1**	Certification pursuant to 18 U.S.C. Section 1350.				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

** Furnished herewith.

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, thereunto duly authorized.

LANTHEUS HOLDINGS, INC.

By:	/s/ MARY ANNE HEINO
Name:	Mary Anne Heino
Title:	*President and Chief Executive Officer (Principal Executive Officer)*
Date:	November 4, 2021

LANTHEUS HOLDINGS, INC.

By:	/s/ ROBERT J. MARSHALL, JR.
Name:	Robert J. Marshall, Jr.
Title:	*Chief Financial Officer and Treasurer (Principal Financial Officer)*
Date:	November 4, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mary Anne Heino, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lantheus Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

Title: *President and Chief Executive Officer*
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert J. Marshall, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lantheus Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

/s/ ROBERT J. MARSHALL, JR.

Name: Robert J. Marshall, Jr.

Title: *Chief Financial Officer and Treasurer*
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Mary Anne Heino, the Chief Executive Officer, and Robert J. Marshall, Jr., the Chief Financial Officer, of Lantheus Holdings, Inc. (the "Company"), hereby certify, that, to their knowledge:

1. The Quarterly Report on Form 10-Q for the period ended September 30, 2021 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2021

/s/ MARY ANNE HEINO
Name: Mary Anne Heino
Title: *President and Chief Executive Officer*
(Principal Executive Officer)

Date: November 4, 2021

/s/ ROBERT J. MARSHALL, JR.
Name: Robert J. Marshall, Jr.
Title: *Chief Financial Officer and Treasurer*
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.