## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## **FORM 10-Q**

(Mark One)

 $\checkmark$ 

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

For the quarterly period ended March 31, 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, <sub>MA</sub>	01862
(Address of principal executive offices)	(Zip Code)

(Address of principal executive offices)

(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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	$\checkmark$	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 67,486,935 shares of common stock, \$0.01 par value, outstanding as of April 27, 2021.

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#### PART I. FINANCIAL INFORMATION

#### Item 1. Financial Statements (Unaudited)

Accumulated other comprehensive loss

Total stockholders' equity

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

	March 31, 2021	Γ	December 31, 2020
Assets			
Current assets			
Cash and cash equivalents	\$ 68,861	\$	79,612
Accounts receivable, net	58,991		54,002
Inventory	30,357		35,744
Other current assets	10,145		9,625
Assets held for sale			5,242
Total current assets	 168,354		184,225
Property, plant and equipment, net	118,381		120,171
Intangibles, net	371,331		376,012
Goodwill	61,189		58,632
Deferred tax assets, net	62,832		70,147
Other long-term assets	61,361		60,634
Total assets	\$ 843,448	\$	869,821
Liabilities and stockholders' equity		-	
Current liabilities			
Current portion of long-term debt and other borrowings	\$ 10,251	\$	20,701
Accounts payable	19,099		16,284
Accrued expenses and other liabilities	35,240		41,726
Liabilities held for sale			1,793
Total current liabilities	 64,590	-	80,504
Asset retirement obligations	14,408		14,020
Long-term debt, net and other borrowings	171,474		197,699
Other long-term liabilities	64,857		63,393
Total liabilities	 315,329		355,616
Commitments and contingencies (See Note 18)			
Stockholders' equity			
Preferred stock (\$0.01 par value, 25,000 shares authorized; no shares issued and outstanding)			
Common stock (\$0.01 par value, 250,000 shares authorized; 67,434 and 66,875 shares issued and outstanding, respectively)	674		669
Additional paid-in capital	669,623		665,530
Accumulated deficit	(140,938)		(149,946)

Total liabilities and stockholders' equity

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

(1, 240)

528,119

843,448

\$

\$

(2,048)

514,205

869,821

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

	Three Months Ended March 31,			
	2021		2020	
Revenues	\$ 92,509	\$	90,704	
Cost of goods sold	 51,479		52,702	
Gross profit	 41,030		38,002	
Operating expenses				
Sales and marketing	14,173		10,130	
General and administrative	16,138		16,699	
Research and development	 10,360		4,048	
Total operating expenses	40,671		30,877	
Gain on sale of assets	 15,263			
Operating income	15,622		7,125	
Interest expense	2,718		1,946	
Gain on extinguishment of debt	(889)			
Other income	 (549)		(350)	
Income before income taxes	14,342		5,529	
Income tax expense	 5,334		2,192	
Net income	\$ 9,008	\$	3,337	
Net income per common share:	 			
Basic	\$ 0.13	\$	0.08	
Diluted	\$ 0.13	\$	0.08	
Weighted-average common shares outstanding:	 			
Basic	 67,094		39,433	
Diluted	 67,714		40,102	

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 March 31,			
	2021 2020			2020
Net income	\$	9,008	\$	3,337
Other comprehensive income (loss):				
Foreign currency translation		102		(446)
Unrealized gain (loss) on cash flow hedges, net of tax		706		(988)
Total other comprehensive income (loss)		808		(1,434)
Comprehensive income	\$	9,816	\$	1,903

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)

	Three Months Ended March 31, 2021								
	Commo	n Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity			
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			

	Three Months Ended March 31, 2020									
	Commo	on Stock	_	Additional Paid-In		Accumulated	Accumulated Other Comprehensive		Total Stockholders'	
	Shares	Shares Amount		Capital		Deficit	Loss		Equity	
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	

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)

	Three Months Ended March 31,		
		2021	2020
Operating activities			
Net income	\$	9,008	\$ 3,337
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation, amortization and accretion		8,123	3,732
Impairment of long-lived assets		—	7,275
Amortization of debt related costs		(61)	169
Changes in fair value of contingent assets and liabilities		300	—
Gain on extinguishment of debt		(889)	_
Provision for excess and obsolete inventory		1,395	449
Stock-based compensation		3,317	3,075
Gain on sale of assets		(15,263)	—
Deferred taxes		4,581	1,467
Long-term income tax receivable		(573)	(554)
Long-term income tax payable and other long-term liabilities		728	705
Other		655	654
Increases (decreases) in cash from operating assets and liabilities:			
Accounts receivable		(2,346)	(1,750)
Inventory		3,889	(2,098)
Other current assets		(536)	1,149
Accounts payable		4,110	(913)
Accrued expenses and other liabilities		(6,620)	(7,289)
Net cash provided by operating activities		9,818	9,408
Investing activities			
Capital expenditures		(2,520)	(2,698)
Proceeds from sale of assets, net		15,823	_
Net cash provided by provided by (used in) investing activities		13,303	(2,698)
Financing activities		<u> </u>	
Payments on long-term debt and other borrowings		(35,572)	(2,551)
Proceeds from stock option exercises		2,043	_
Proceeds from issuance of common stock		337	366
Payments for minimum statutory tax withholding related to net share settlement of equity awards		(1,599)	(1,547)
Net cash used in financing activities		(34,791)	(3,732)
Effect of foreign exchange rates on cash, cash equivalents and restricted cash		(21)	(184)
Net (decrease) increase in cash, cash equivalents and restricted cash		(11,691)	2,794
Cash, cash equivalents and restricted cash, beginning of period		82,694	92,919
Cash, cash equivalents and restricted cash, end of period	\$	· · · ·	\$ 95,713
Cush, cush equivalents and restricted cush, that of period	φ	/ 1,005	ψ 55,715

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

	 Three Mor Mar	
	2021	2020
Reconciliation to amounts within the condensed consolidated balance sheets		
Cash and cash equivalents	\$ 68,861	\$ 95,713
Restricted cash included in other long-term assets	2,142	
Cash, cash equivalents and restricted cash at end of period	\$ 71,003	\$ 95,713

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, June 19, 2020), 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 months ended March 31, 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 19, "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 of 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, currently a late stage clinical candidate ("PyL"). 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 PyL 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. 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. As a result of the COVID-19 pandemic, the Company undertook a thorough analysis of all of its discretionary expenses. In the first quarter of 2020, the Company implemented certain cost reduction initiatives. For most of the second quarter, 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 Phase 2 trial of 1095 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 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.

The on-going impact of the COVID-19 pandemic on the Company's business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, and the extent and severity of the impact on the Company's customers and suppliers, all of which remain uncertain and cannot be predicted. While the impact of COVID-19 on the Company's results of operations and cash flows has been, and is expected to continue to be, material, given the continually evolving nature 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 consolidated statement 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 March 31, 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 Adopte	d During the Three Months Ended March 31, 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:

1

Three Months Ended March 31,							
	2021		2020				
\$	87,319	\$	90,213				
	5,190		491				
\$	92,509	\$	90,704				
	\$ \$	Marc           2021           \$ 87,319           5,190	March 31           2021           \$ 87,319 \$           5,190				

(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 of 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 of AZEDRA and other oncologic therapeutics. Strategic partnerships and other includes partnerships related to other products, such as RELISTOR, that improve patient outcomes and care.

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

	Three Months Ended March 31,					
(in thousands)		2021	2020 <sup>(1)</sup>			
DEFINITY	\$	55,971	\$	52,505		
TechneLite		22,800		22,779		
Other precision diagnostics		6,984		13,057		
Total precision diagnostics		85,755		88,341		
Radiopharmaceutical oncology		1,500		1,968		
Strategic partnerships and other		5,254		395		
Total revenues	\$	92,509	\$	90,704		

<sup>(1)</sup> The Company reclassified rebates and allowances of \$4.7 million for the three months ended March 31, 2020 within each product category, which included \$4.3 million for DEFINITY, \$0.3 million for TechneLite and \$0.1 million for other precision diagnostics.

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 are 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.

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

	March 31, 2021								
<u>(in thousands)</u>	r	Total Fair Value		Level 1		Level 2	Level 3		
Assets:									
Money market	\$	39,416	\$	39,416	\$	—	\$	—	
Contingent receivable		12,200		—				12,200	
Total assets	\$	51,616	\$	39,416	\$	—	\$	12,200	
Liabilities:									
Interest rate swaps	\$	960	\$	_	\$	960	\$	_	
Contingent consideration liabilities		17,000		_		_		17,000	
Total liabilities	\$	17,960	\$	_	\$	960	\$	17,000	
				Decembe	r 31	, 2020			
		Fotal Fair			r 31	-			
(in thousands)		Fotal Fair Value	_	Decembe	r 31	, 2020 Level 2		Level 3	
Assets:		Value	-	Level 1		-		Level 3	
Assets: Money market	\$	<b>Value</b> 35,457	\$		r 31	-	\$	_	
Assets: Money market Contingent receivable		Value 35,457 11,300	-	Level 1 35,457 —	\$	-	\$		
Assets: Money market		<b>Value</b> 35,457	\$	Level 1		-	\$ \$	_	
Assets: Money market Contingent receivable		Value 35,457 11,300	-	Level 1 35,457 —	\$	-	\$ \$		
Assets: Money market Contingent receivable Total assets		Value 35,457 11,300	-	Level 1 35,457 —	\$	-	\$ \$ \$		
Assets: Money market Contingent receivable Total assets Liabilities:	\$ \$	Value 35,457 11,300 46,757	\$	Level 1 35,457 —	\$ \$	Level 2 — — —	\$		

During the three months ended March 31, 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 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 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 or the probabilities as to the periods in which milestones will be achieved 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 following tables summarize quantitative information and assumptions pertaining to the fair value measurement of assets and liabilities using Level 3 inputs at March 31, 2021.

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		Fair V	Valu	e at			Assur	nptions
<u>(in thousands)</u>	Marc	h 31, 2021	]	December 31, 2020	Valuation Technique	Unobservable Input	March 31, 2021	December 31, 2020
Contingent receivable:								
Regulatory milestone	¢	2 200	¢	2 200	Probability adjusted discounted cash flow	Period of expected milestone	2021	2024
	\$	3,200	\$	3,200	model	achievement	2021	
						Probability of success	90 %	
<b>.</b>					~ 1 1 1 1 1	Discount rate	23 %	24 %
Royalties		9,000		8,100	Probability adjusted discounted cash flow model			
						Probability of success	13% - 77%	13% - 77%
						Discount rate	23 %	
Total	\$	12,200	\$	11,300				
		,	-	,				
		F	air '	Value at December 31			Assu	mptions
<u>(in thousands)</u>	Μ	larch 31, 2	021	2020	Valuation Techniq	ue Unobservable Input	March 31, 2021	December 31, 2020
Contingent considera liability:	ation							
Net sales targets - PyL (CVRs)	۔ \$	4.6	600	\$ 4,20	Monte-Carlo simulation	Period of expected milestone achievement	2022 - 2023	2022 - 2023
	ψ	4,0	000	φ 4,20	10	Discount rate	2022 - 2023	2022 - 2023
1095 commercialization milestone	on	2.1	00	2,20	Probability adjusted discounted cash flo model	1	23 /0	24 /0
		_,_		_,		Period of expected milestone achievement	2026	2026
						Probability of success	45 %	45 %
						Discount rate	1.0 %	0.5 %
Net sales targets - AZEDRA and 1095		10,3	00	9,40	Monte-Carlo 0 simulation			
						Probability of success	40% - 100%	40% - 100%
						Discount rate	22% - 23%	23% - 24%
Total	\$	17,0	000	\$ 15,80	00			

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

	<b>Financial Assets</b>	<b>Financial Liabilities</b>
( <u>in thousands)</u>	 Three Months Ended March 31, 2021	 Three Months Ended March 31, 2021
Fair value, beginning of period	\$ 11,300	\$ 15,800
Changes in fair value included in net income	900	1,200
Fair value, end of period	\$ 12,200	\$ 17,000

The change in fair value of the contingent financial asset and contingent financial liabilities resulted in a loss of \$0.3 million for the three months ended March 31, 2021 and was primarily due to changes in market conditions and the passage of time.

#### 5. Income Taxes

The Company provides for income taxes at the end of each interim period based on the estimated effective tax rate for the full year, adjusted for any discrete events which are recorded in the period they occur. Cumulative adjustments to the tax provision are recorded in the interim period in which a change in the estimated annual effective tax rate is determined. The Company's income tax expense is presented below:

	Three Months Ended March 31,				
<u>(in thousands)</u>	2021		2020		
Income tax expense	\$ 5,334	\$	2,192		

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 deferred state tax credits 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 \$2.3 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 taxing authorities. Accordingly, a long-term receivable is recorded to account for the expected value to the Company of future indemnification payments, net of actual tax benefits received, to be paid on behalf of the Company by BMS. The tax indemnification receivable is recorded within other long-term assets.

In accordance with the Company's accounting policy, the change in the tax liability, 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, adjustments are included in income tax expense while the offsetting adjustment is included in other income. Assuming that the 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.

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 research credits 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 a net overall deferred tax liability for Progenics after the application of acquisition accounting.

During the current period, the Company finalized the acquisition accounting for income taxes resulting in a reduction of deferred tax assets, primarily related to state research credits and an increase to goodwill of \$2.6 million.

#### 6. Inventory

Inventory consisted of the following:

<u>(in thousands)</u>	March 31, 2021	December 31, 2020		
Raw materials	\$ 15,297	\$	16,000	
Work in process	8,606		11,212	
Finished goods	6,454		8,532	
Total inventory	\$ 30,357	\$	35,744	

#### 7. Property, Plant and Equipment, Net

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

<u>(in thousands)</u>	March 31, 2021			December 31, 2020
Land	\$	13,450	\$	13,450
Buildings		71,622		70,381
Machinery, equipment and fixtures		79,460		77,854
Computer software		23,751		23,644
Construction in progress		9,638		11,254
		197,921		196,583
Less: accumulated depreciation and amortization		(79,540)		(76,412)
Total property, plant and equipment, net	\$	118,381	\$	120,171

Depreciation and amortization expense related to property, plant and equipment, net, was \$3.0 million for the three months ended March 31, 2021 and 2020.

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 March 31, 2020, as a result of a decline in expected future cash flows and the effect of COVID-19 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 three months ended March 31, 2020 in cost of goods sold in the condensed consolidated statement of operations.

#### 8. Business Combinations

On June 19, 2020, the Company completed the Progenics Acquisition. Progenics is an oncology company developing innovative medicines and artificial intelligence to Find, Fight and Follow cancer. The acquisition combined the commercialization, supply chain and manufacturing expertise of the Company with the currently commercialized products and research and development ("R&D") pipeline of Progenics. Progenics brings to the Company several commercial products and a pipeline of product candidates that will further diversify the Company's commercial and clinical development portfolios.

Under the terms of the Merger Agreement, the Company acquired all of 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 Replacement Stock Options related to precombination services was recorded as a component of consideration transferred. Finally, as a result of the 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:

<u>(in thousands)</u>	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 <sup>(1)</sup>	\$	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 Acquisition Date (as previously reported)		Measurement Period Adjustments	Acquisit	cognized as of ion Date justed)
Cash and cash equivalents	\$ 15,4	21	\$	\$	15,421
Accounts receivable	5,7	87			5,787
Inventory	9	15	160		1,075
Other current assets	3,2	50	434		3,684
Property, plant and equipment	14,9	72	_		14,972
Identifiable intangible assets (weighted average useful life):					
Currently marketed product (15 years)	142,1	00	800		142,900
Licenses (11.5 years)	87,5	00	(1,700)		85,800
Developed technology (9 years)	3,0	00	(600)		2,400
IPR&D	150,9	00	200		151,100
Other long-term assets	37,6	31	_		37,631
Accounts payable	(1,6	16)	_		(1,616)
Accrued expenses and other liabilities	(8,2	07)	(80)		(8,287)
Other long-term liabilities	(30,7	78)	(380)		(31,158)
Long-term debt and other borrowings	(40,2	00)	—		(40,200)
Deferred tax liabilities	(3,7	17)	(2,258)		(5,975)
Goodwill	42,0	51	3,424		45,475
Total consideration transferred	\$ 419,0	09	\$	\$	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.

#### 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 of 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, and will also include a working capital adjustment once settled. 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 Q1 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 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 statement of operations for the three months ended March 31, 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 March 31, 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:

<u>(in thousands)</u>	Α	mount
Balance at January 1, 2021	\$	14,020
Accretion expense		388
Balance at March 31, 2021	\$	14,408

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:

	March 31, 2021									
<u>(in thousands)</u>	Amortization Method		Cost		Accumulated Amortization		Net			
Trademarks	Straight-Line	\$	13,540	\$	(11,096)	\$	2,444			
Customer relationships	Accelerated		96,941		(94,055)		2,886			
Currently marketed product	Straight-Line		142,900		(7,434)		135,466			
Licenses	Straight-Line		85,800		(5,895)		79,905			
Developed technology	Straight-Line		2,400		(210)		2,190			
IPR&D	N/A		148,440		—		148,440			
Total		\$	490,021	\$	(118,690)	\$	371,331			

	December 31, 2020						
<u>(in thousands)</u>	Amortization Method		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 \$4.7 million and \$0.4 million for the three months ended March 31, 2021 and 2020, respectively.

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

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<u>(in thousands)</u>	Amount	
Remainder of 2021	\$ 1	14,051
2022	1	18,477
2023	1	17,878
2024	1	17,808
2025	1	17,753
2026 and thereafter	13	36,924
Total	\$ 22	22,891

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

As of March 31, 2021, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

<u>(in thousands)</u>	1	Amount
Remainder of 2021	\$	7,500
2022		11,250
2023		15,000
2024		148,750
Total principal outstanding		182,500
Unamortized debt discount		(647)
Unamortized debt issuance costs		(559)
Finance lease liabilities		431
Total		181,725
Less: current portion		(10,251)
Total long-term debt, net and other borrowings	\$	171,474

At March 31, 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 3.4%.

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 March 31, 2021, accumulated other comprehensive loss included \$0.6 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 sheet:

<u>(in thousands)</u>		March 31, 2021		December 31, 2020		
Derivatives type	Classification					
Liabilities:						
Interest rate swap	Accrued expenses and other liabilities	\$	960	\$	1,908	

#### 14. Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss, net of tax of \$0.2 million and \$0.3 million for the three months ended March 31, 2021 and 2020, respectively, consisted of the following:

<u>(in thousands)</u>	eign currency ranslation	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	102		533		635
Amounts reclassified to earnings			173		173
Balance at March 31, 2021	\$ (528)	\$	(712)	\$	(1,240)
Balance at January 1, 2020	\$ (960)	\$		\$	(960)
Other comprehensive loss before reclassifications	(446)		(988)		(1,434)
Amounts reclassified to earnings	 				
Balance at March 31, 2020	\$ (1,406)	\$	(988)	\$	(2,394)

#### 15. Stock-Based Compensation

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

		Ended ,		
<u>(in thousands)</u>		2021		2020
Cost of goods sold	\$	622	\$	618
Sales and marketing		350		253
General and administrative		1,920		1,815
Research and development		425		389
Total stock-based compensation expense	\$	3,317	\$	3,075

#### 16. Net Income Per Common Share

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

		Three Months Ended March 31,				
<u>(in thousands, except per share amounts)</u>	2021			2020		
Net income	\$	9,008	\$	3,337		
Basic weighted-average common shares outstanding		67,094		39,433		
Effect of dilutive stock options		82		28		
Effect of dilutive restricted stock		538		641		
Diluted weighted-average common shares outstanding		67,714		40,102		
Basic income per common share	\$	0.13	\$	0.08		
Diluted income per common share	\$	0.13	\$	0.08		
Antidilutive securities excluded from diluted net income per common share		1,349		604		

#### 17. Other Income

Other income consisted of the following:

	Three Months Ended March 31,				
<u>(in thousands)</u>	2021 2020				
Foreign currency losses	\$ 42	\$	314		
Tax indemnification income, net	(573)		(555)		
Interest income	(17)	1	(109)		
Other	(1)		—		
Total other income	\$ (549)	\$	(350)		

#### **18.** 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 March 31, 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 by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH. Between May 11, 2017 and July 4, 2017, the opposition division provided notice that the three European patents would be revoked. Each of these matters were appealed to with the European Patent Office. 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. Oral proceedings for the third patent, EP1615646 were held on September 22, 2020. The decision under appeal was set aside and the case was remitted to the opposition division for further prosecution. The deadline for

written submissions prior to an oral hearing is July 27, 2021. The oral hearing is set for September 27, 2021. Because the outcome of litigation 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 European Patent Office ("EPO") stay the examination of a certain European Patent (EP) 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. 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 the aforementioned 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 United States Patent and Trademark Office. 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). On February 9, 2021, the PTAB mailed a Notice of Filing Date Accorded to Petition and Time for Filing Patent Owner Preliminary Response. The PTAB set a three (3) month deadline for MIP to file a preliminary response. The filing of a preliminary response to the petition is optional for the patent owner (MIP). Should the PTAB decide to institute post-grant review, a schedule will be set and MIP will be afforded three months from the date of institution to formally respond to the petition. Because the outcome of litigation is uncertain, the Company cannot predict how or when this matter will be ultimately resolved.

#### **19. 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 Note 8, and the sale of the Puerto Rico subsidiary in the current quarter, which resulted in a change in operating and reportable segments. As of the first quarter of fiscal year 2021, the Company 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.

#### 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 Ouarterly Report on Form 10-O 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 include words such as "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects," "should," "could," "predicts," "hopes" and similar expressions. 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, and on the timing and enrollment of our clinical trials; (ii) continued market expansion and penetration for our commercial products, particularly DEFINITY, in the face of segment competition and potential generic competition as a result of patent and regulatory exclusivity expirations; (iii) our efforts in new product development, including for PyL, our prostate cancer diagnostic imaging agent, including our ability to obtain U.S. Food and Drug Administration ("FDA") approval of PyL in 2021, and new clinical applications for our products; (iv) our dependence upon third parties for the manufacture and supply of PyL and the timing of that manufacturing capacity becoming available; (v) the global Molybdenum-99 ("Mo-99") supply; (vi) our products manufactured at Jubilant HollisterStier ("JHS") and our recently-approved modified formulation of DEFINITY ("DEFINITY RT") to be commercially manufactured at Samsung Biologics ("SBL"); (vii) the continued integration of the Progenics product and product candidate portfolio into our business following the June 2020 consummation of the Progenics Acquisition; (viii) our ability to use in-house manufacturing capacity; (ix) the expected timing for commercialization of products we or our strategic partners may develop, including flurpiridaz F 18; and (x) 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.

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 www.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.

#### Overview



#### **Our Business**

We are an established leader and fully integrated provider of 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 improved 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, 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 current quarter, which resulted in a change in our operating segments to one reportable business segment.

#### **Progenics Acquisition**

On June 19, 2020, we completed the Progenics Acquisition. Progenics is an oncology company focused on developing and commercializing innovative targeted medicines and artificial intelligence to Find, Fight and Follow cancer. Progenics' portfolio of products and product candidates includes, among other things, therapeutic agents designed to target cancer (AZEDRA, 1095 and PSMA TTC), diagnostic imaging agents designed to target PSMA for prostate cancer (PyL and 1404), RELISTOR for opioid-induced constipation ("OIC"), AI imaging technologies and leronlimab being developed for HIV infection and COVID-19 applications. Progenics' current revenue is 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.

Lantheus Holdings issued 26,844,877 shares of Lantheus Holdings common stock and 86,630,633 CVRs to former Progenics stockholders in connection with the Progenics Acquisition. Lantheus Holdings also assumed 34,000 in-the-money Progenics stock options and 6,507,342 out-of-the-money Progenics stock options, each converted into Replacement Stock Options at an exchange ratio of 0.31.

#### **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 June 19, 2020 Progenics Acquisition date. We also expect that the anticipated approval and launch of PyL during fiscal year 2021 may 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. Even with this recent change, we expect Xenon sales to continue to be at reduced levels for at least as long as COVID-19 precautions remain in place, and 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 of 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 Phase 2 trial 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.

While we are currently unable to estimate the impact of COVID-19 on our overall 2021 operations and financial results, we ended the first quarter of 2021 with \$68.9 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 PyL 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 2021, 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 May 2021 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least November 2023. 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 later in 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 *New 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.
- *New 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.
  - In April 2019, we announced a strategic development and commercial collaboration with 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. Retinal vein occlusion is one of the most common causes of vision loss worldwide.
  - In December 2019, we announced a strategic commercial supply agreement with CarThera for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma. Glioblastoma is a lethal and devastating form of brain cancer with median survival of 15 months after diagnosis.
  - In October 2020, we announced a strategic collaboration with 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 the investment in these efforts 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 currently expect to make use of this in-house manufacturing capability in late 2021, although 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.

#### PyL FDA Approval and Commercial Launch

PyL (also known as 18F-DCFPyL) is a fluorine 18-based PET imaging agent that targets prostate specific membrane antigen (PSMA), enabling visualization of primary tumors as well as bone and soft tissue metastases, with potential high clinical utility in the detection of recurrent and/or metastatic prostate cancer. Progenics has completed a clinical development program that consisted of two pivotal clinical studies, which were designed to provide robust, prospective, well-controlled, and pathology- or composite truth standard-verified data to establish the safety and diagnostic performance of PyL across the disease continuum of prostate cancer. The results from these studies provide data in support of the potential of PyL to reliably detect and localize disease, including in patients with low PSA values, and may help enable appropriate disease management, thus supporting the potential use for detection of recurrent or metastatic prostate cancer. We filed the PyL New Drug Application ("NDA") with the FDA in September 2020 and received notice of priority review in December 2020 with a Prescription Drug User Fee Act ("PDUFA") date of May 28, 2021. If the FDA grants approval of the PyL NDA as of the PDUFA date, we could commence our commercial launch of PyL shortly thereafter, although there can be no assurances that the FDA will act by the PDUFA date or determine that the clinical study results we have presented are sufficient or convincing to obtain FDA approval.

The commercial launch of PyL will be complex and expensive. We are in the process of hiring additional employees to assist us with the commercialization of PyL including in the areas of sales, marketing, reimbursement, quality and medical affairs. To manufacture PyL, we are currently creating a field-based network of specialized PET manufacturing facilities ("PMFs"), with radioisotope-producing cyclotrons that produce fluorine-18 ("F 18"), which has a 110 minute half-life, requiring that PyL be 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 PyL, which is next transferred to a radiopharmacist who prepares and dispenses patient-specific doses from the final product. Because each of the PMFs manufacturing these products will be deemed by the FDA to be a separate manufacturing site, each will have to be approved by the FDA, and we can give no assurance that the FDA will do this in accordance with our planned roll-out schedule for the products. In our PyL NDA, we included a limited number of PMFs for approval, and we intend to add in a sequenced manner, using FDA site approval processes, additional PMFs to our manufacturing network in the months following FDA product approval with the goal of having broad availability for the U.S. population within six months of product approval. If we are delayed in our PyL commercial launch by FDA approval of our manufacturing sites or other challenges, our future business, results of operations, financial condition and cash flows could be adversely affected.

In addition, obtaining adequate reimbursement for PyL will be critical, including not only coverage from Medicare, Medicaid, 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, even if PyL obtains regulatory approval, that adequate reimbursement can be secured to allow PyL to become successfully commercialized.

#### **Global Mo-99 Supply**

We currently have Mo-99 supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2022, and renewable by us on a year-to-year basis thereafter, and with NTP Radioisotopes ("NTP") and the Australian Nuclear Science and Technology Organisation ("ANSTO"), running through December 31, 2021. 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 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



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.

We have also completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility, which will also allow us to optimize our costs and reduce our supply chain risk. We can give no assurance as to when or if we will be successful in these efforts or that we will be able to successfully manufacture any additional commercial products at our North Billerica, Massachusetts facility.

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

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. If we are unable to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits may not be realized fully or at all, or may take longer to realize than expected, and the value of our common stock may suffer.

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.

We have incurred, and expect to continue to incur, substantial expenses in connection with the integration of the Progenics business with our own. There are a large number of processes, policies, procedures, operations, technologies and systems that have been, or must be, integrated, including purchasing, accounting and finance, sales, payroll, pricing, revenue management, marketing and benefits. The substantial majority of these costs have been, and will continue to be, non-recurring expenses related to the Progenics Acquisition, facilities and systems consolidation costs. We may also incur additional costs to maintain employee morale and to attract, motivate or retain management personnel or key employees.

#### **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 brings additional and substantial clinical development expense. The PyL NDA filed with the FDA on September 29, 2020, was accepted and granted priority review with PDUFA action date of May 28, 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. 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's development activities for PSMA AI are on-going. 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.

#### New 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. As the Progenics Acquisition indicates, 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 is housed within the strategic partnerships and
  other revenue 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 Noria Therapeutics, Inc. ("Noria") 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, Noria will drive the early clinical development of NTI-1309. Upon successful completion of the Phase 1 study which we believe will start later in 2021, NTI-1309 will be integrated into our portfolio of imaging biomarkers and included in our Pharma Services offering. We will also then assess options to bring NTI-1309 to market through our own clinical trials, as a diagnostic or potentially a therapeutic agent.
- We have also expanded our Pharma Services offering to include PyL for pharmaceutical companies developing PSMA-targeted therapies and have entered into PyL clinical supply agreements with each of Regeneron, Bayer and POINT BioPharma for use of PyL in prostate cancer drug development programs.

We can give no assurance as to when or if any of these Pharma Services collaborations 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 March 31,					
<u>(in thousands)</u>		2021		2020	0	Change \$	Change %
Revenues	\$	92,509	\$	90,704	\$	1,805	2.0 %
Cost of goods sold		51,479		52,702		(1,223)	(2.3)%
Gross profit		41,030		38,002		3,028	8.0 %
Operating expenses							
Sales and marketing		14,173		10,130		4,043	39.9 %
General and administrative		16,138		16,699		(561)	(3.4)%
Research and development		10,360		4,048		6,312	155.9 %
Total operating expenses		40,671		30,877		9,794	31.7 %
Gain on sale of assets		15,263				15,263	N/A
Operating income		15,622		7,125		8,497	119.3 %
Interest expense		2,718		1,946		772	39.7 %
Gain on extinguishment of debt		(889)				(889)	N/A
Other income		(549)		(350)		(199)	56.9 %
Income before income taxes		14,342		5,529		8,813	159.4 %
Income tax expense		5,334		2,192		3,142	143.3 %
Net income	\$	9,008	\$	3,337	\$	5,671	169.9 %

#### Comparison of the Periods Ended March 31, 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 of AZEDRA and other oncologic therapeutics. Strategic partnerships and other includes partnerships related to other products, such as RELISTOR, that improve patient outcomes and care. Revenues are summarized by product category on a net basis as follows:

	Three Months Ended March 31,						
(in thousands)		2021		2020 <sup>(1)</sup>		hange \$	Change %
DEFINITY	\$	55,971	\$	52,505	\$	3,466	6.6 %
TechneLite		22,800		22,779		21	0.1 %
Other precision diagnostics		6,984		13,057		(6,073)	(46.5)%
Total precision diagnostics		85,755		88,341		(2,586)	(2.9)%
Radiopharmaceutical oncology		1,500		1,968		(468)	(23.8)%
Strategic partnerships and other		5,254		395		4,859	1,230.1 %
Total revenues	\$	92,509	\$	90,704	\$	1,805	2.0 %

(1)

) We reclassified rebates and allowances of \$4.7 million for the three months ended March 31, 2020 within each product category, which included \$4.3 million for DEFINITY, \$0.3 million for TechneLite and \$0.1 million for other precision diagnostics.

The increase in revenues for the three months ended March 31, 2021, as compared to the prior year period, is primarily driven by DEFINITY volume increases and the addition of the Progenics product portfolio. 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)	tes and wances
Balance, January 1, 2021	\$ 9,350
Provision related to current period revenues	5,838
Adjustments relating to prior period revenues	23
Payments or credits made during the period	(5,756)
Balance, March 31, 2021	\$ 9,455

#### **Gross Profit**

The increase in gross profit for the three months ended March 31, 2021, as compared to the prior year period is primarily due to an asset impairment loss of \$7.3 million on other nuclear products that occurred in the prior year and DEFINITY volume increases. 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 \$4.0 million for the three months ended March 31, 2021 as compared to the prior year period. This was primarily driven by the integration of the Progenics sales and marketing organization as well as preparation activities for the launch of PyL.

#### 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 decreased \$0.6 million for the three months ended March 31, 2021 as compared to the prior year period. This was primarily driven by acquisition-related costs associated with the Progenics Acquisition in the prior year. This decrease is partially offset by higher headcount related costs post-acquisition.

#### **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 increased \$6.3 million for the three months ended March 31, 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 PyL and 1095.

#### 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 three months ended March 31, 2021.

#### Interest Expense

Interest expense increased by approximately \$0.8 million for the three months ended March 31, 2021 as compared to the prior year period due to the Royalty-Backed loan we assumed as part of the Progenics Acquisition.

#### Gain on Extinguishment of Debt

For the three months ended March 31, 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.

#### **Income Tax Expense**

The income tax expense recorded for the three months ended March 31, 2021 was primarily due to the pre-tax income reported during the quarter, partially offset by the accrual of interest associated with uncertain tax positions.

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:

	Three Months Ended March 31,		
	2021	2020	
Effective tax rate	37.2%	39.6%	

Our effective tax rate in fiscal 2021 differs from the U.S. statutory rate of 21% principally due to state income taxes and the accrual of interest on uncertain tax positions, offset by the benefit created by stock compensation expense and tax credits.

The decrease in the effective income tax rate for the three months ended March 31, 2021 as compared to the prior year period is primarily due to the increased amount of pre-tax income and a higher tax benefit of stock compensation deductions in the current three month period, offset by an increase in the effective tax rate due primarily to the impact of the Progenics Acquisition on the combined Company's effective state tax rate.

#### Liquidity and Capital Resources

#### Cash Flows

The following table provides information regarding our cash flows:

	Three Months Ended March 31,			
<u>(in thousands)</u>		2021		2020
Net cash provided by operating activities	\$	9,818	\$	9,408
Net cash provided by provided by (used in) investing activities	\$	13,303	\$	(2,698)
Net cash used in financing activities	\$	(34,791)	\$	(3,732)

#### Net Cash Provided by Operating Activities

Net cash provided by operating activities of \$9.8 million in the three months ended March 31, 2021 was driven primarily by net income of \$9.0 million, depreciation, amortization and accretion expense of \$8.1 million, stock-based compensation expense of \$3.3 million, and deferred income taxes of \$4.6 million. These net sources of cash were offset by a gain on sale of assets of \$15.3 million and a net decrease of \$1.5 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 increased receivables from sales offset by a reduction in inventory due to obsolescence as well as the timing of inventory purchases.

Net cash provided by operating activities of \$9.4 million in the three months ended March 31, 2020 was driven primarily by net income of \$3.3 million plus \$3.7 million of depreciation, amortization and accretion expense, impairment of long-lived assets of \$7.3 million, stock-based compensation expense of \$3.1 million, and changes in deferred taxes of \$1.5 million. These net sources of cash were offset by a net decrease of \$10.9 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.

#### Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities during the three months ended March 31, 2021 was primarily due to cash proceeds of \$15.8 million received from the sale of our Puerto Rico subsidiary, which was offset by \$2.5 million of capital expenditures.

Net cash used in investing activities during the three months ended March 31, 2020 reflected \$2.7 million in capital expenditures.

#### Net Cash Used in Financing Activities

Net cash used in financing activities during the three months ended March 31, 2021 is primarily attributable to the payments on long-term debt and other borrowings of \$35.6 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 \$1.6 million offset by proceeds of \$2.0 million from stock option exercises.

Net cash used in financing activities during the three months ended March 31, 2020 is primarily attributable to the payments on long-term debt and other borrowings of \$2.5 million related to the 2019 Term Facility and payments for minimum statutory tax withholding related to net share settlement of equity awards of \$1.5 million, offset by proceeds of \$0.4 million from the issuance of our common stock.

#### **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	
Q1 2021		5.50 to 1.00	
Q2 2021		3.75 to 1.00	
Thereafter		3.50 to 1.00	
	Period	Interest Coverage Ratio	
Q1 2021		2.00 to 1.00	
Thereafter		3.00 to 1.00	

The Amendment also introduces a new financial covenant requiring Consolidated Liquidity (as defined in the Amended Credit Agreement) to be no less than \$150.0 million. The Consolidated Liquidity covenant is tested on a continuing basis beginning on the date of the Amendment and ending on the date on which we deliver a compliance certificate for the fiscal quarter ending March 31, 2021. As of March 31, 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 is 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 matured 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.

Under the terms of the loan agreement, payments of interest and principal, if any, were made on the last day of each calendar quarter out of RELISTOR royalty payments received since the immediately-preceding payment date. On each payment date, 50% of RELISTOR royalty payments received since the immediately-preceding payment date in excess of accrued interest on the loan were used to repay the principal of the loan, with the balance retained by us. 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 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 the newly acquired Progenics assets AZEDRA, PyL, 1095, 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;
- 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 March 31, 2021, our only current committed external source of funds is our borrowing availability under our 2019 Revolving Facility. We had \$68.9 million of cash and cash equivalents at March 31, 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 PyL 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 require 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 three months ended March 31, 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 three months ended March 31, 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 18, "Commitments and Contingencies", to the 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:

#### 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.

#### 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 March 31, 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	Av	Total Number of Shares Purchased as Average Price Paid Part of Publicly per Share Announced Programs		Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program	
January 2021**	382	\$	13.49	*	*	
February 2021**	17,855	\$	18.74	*	*	
March 2021**	67,014	\$	18.79	*	*	
Total	85,251			*		

\* 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**

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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**

None.



#### Item 6. Exhibits

		INCORPORATED BY REFERENCE			
EXHIBIT NUMBER	DESCRIPTION OF EXHIBITS	FORM	FILE NUMBER	EXHIBIT	FILING DATE
10.1	Consulting Agreement by and between Lantheus Medical Imaging, Inc. and Michael P. Duffy, dated as of March 31, 2021	8-K	001-36569	10.1	April 1, 2021
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:	May 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 and Principal Accounting Officer)
Date:	May 4, 2021

#### 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;
  - 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.

/s/ MARY ANNE HEINO

Date: May 4, 2021

Name: Title:

Mary Anne Heino President and Chief Executive Officer (Principal Executive Officer)

#### 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:
  - 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;
  - 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: May 4, 2021

#### /s/ ROBERT J. MARSHALL, JR.

 Name:
 Robert J. Marshall, Jr.

 Title:
 Chief Financial Officer and Treasurer

 (Principal Financial Officer and Principal Accounting Officer)

#### 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 March 31, 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: May 4, 2021

Name: Title:

Mary Anne Heino President and Chief Executive Officer (Principal Executive Officer)

/s/ MARY ANNE HEINO

Date: May 4, 2021

#### /s/ ROBERT J. MARSHALL, JR.

Name: Ro Title: Ch

Robert J. Marshall, Jr. Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting 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.